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TOWARD A PROCESS-BASED APPROACH TO FAILURE-TO-WARN LAW

MICHAEL S. JACOBS*

Over the last thirty years, failure-to-warn law has received little scholarly attention. This lack of discussion most likely stemmed from the courts' apparent ease in applying certain elements of negligence law to determine a manufacturer's liability for failure to warn of risks associated with a product's use. During the last few years, however, commentators have begun to scrutinize closely the apparent success of this branch of products liability law. Closer analysis reveals that failure-to-warn law, this seemingly well-behaved descendant of tort law, is actually a problem child.

In this Article, Associate Professor Michael Jacobs examines the fundamental flaws in the current status of failure-to-warn law. Professor Jacobs finds that the existing rules governing failure-to-warn law are ambiguous, subjective and incapable of precise definition. Specifically, he argues that these definitional problems prohibit courts from placing any meaningful limitations on manufacturer liability, thereby imposing a duty of virtual perfection on the manufacturer. Next, Professor Jacobs critiques the recent works of two commentators which suggest that the problems inherent in the failure-to-warn area may be solved by a content-based approach. Professor Jacobs argues that the commentators' focus on determining the "correct" content of particular warnings is misdirected and ineffective. Instead, he proposes that the courts adopt a process-based approach to failure-to-warn law, focusing on the procedures used by manufacturers prior to adoption and publication of the warning label to determine manufacturer liability.

I. INTRODUCTION

Ever since the successful revolution in products liability law, fail-

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1. Prompted in part by the decision of the New Jersey Supreme Court in Henningsen v. Bloomfield Motors, Inc., 32 N.J. 358, 413, 161 A.2d 69, 99-100 (1960), to abolish the doctrine
ure-to-warn doctrine has seemed the well-behaved child of the post-revolutionary era. For the past thirty years, while courts and commentators have wrestled with the serious theoretical and practical problems posed by the two other components of modern products law, liability for defective manufacture and for defective design, failure-to-warn law has ap-

of privity of contract, the revolution replaced a regime centered on contractual undertakings and the often obscure and usually detailed requirements of express and implied warranties under the law of sales. See, e.g., McCabe v. Liggett Drug Co., 330 Mass. 177, 179-80, 112 N.E.2d 254, 256-57 (1953); Chysky v. Drake Bros. Co., 235 N.Y. 468, 472-73, 139 N.E. 576, 577-78 (1923). The new regime's nature and practice largely resembled torts law. This modern analysis subdivided the area into three distinct types of manufacturer responsibility: liability for injuries caused by defectively made products (regardless of whether the defect could be attributed to any negligence or fault on the part of the manufacturer); liability for injuries caused by products well made but negligently designed; and liability for injuries caused by products deemed defective because unaccompanied by a warning adequately describing the relevant risks of product use or misuse. See generally RESTATEMENT (SECOND) OF TORTS § 402A (1964) (outlining rules of strict liability for defectively made products); RICHARD A. EPSTEIN, MODERN PRODUCTS LIABILITY LAW 1-118 (1980) (examining the development and current status of manufacturer liability for defectively made products). For a contemporaneous and insightful discussion of the history and process of the revolution, see William L. Prosser, The Assault upon the Citadel, 69 YALE L.J. 1099, 1099-138 (1960) [hereinafter Assault]; William L. Prosser, The Fall of the Citadel, 50 MINN. L. REV. 791, 791-814 (1966) [hereinafter Fall].

2. Courts and commentators first struggled with the question whether manufacturers should be liable to bystanders for injuries caused by defectively made products, concluding almost unanimously that they should. See, e.g., Elmore v. American Motors Corp., 70 Cal. 2d 578, 586, 451 P.2d 84, 88-89, 75 Cal. Rptr. 652, 656 (1969); Codling v. Paglia, 32 N.Y.2d 330, 342, 298 N.E.2d 622, 628, 345 N.Y.S.2d 461, 469-70 (1973); see also Harry Kalven, Jr., Tort Law—Tort Watch, 34 J. ASS'N TRIAL LAW. 1, 44-59 (1972) (tracing the development of case law "emphatically in favor of the bystander"); Dix W. Noel, Defective Products: Extension of Strict Liability to Bystanders, 38 TENN. L. REV. 1, 4 (1970) ("Today...there is a strong current of judicial authority in favor of protection of foreseeable bystanders."). Courts and commentators continue to grapple with the issue of whether manufacturers are liable for property damage caused by inherent product defects and, if so, for what types of property damage. See East River S.S. Corp. v. Transamerica Delaval, 476 U.S. 858, 867-68 (1986); Richard E. Speidel, Warranty Theory, Economic Loss, and the Privity Requirement: Once More into the Void, 67 B.U. L. REV. 9, 11-27 (1987).


peared to function tolerably well without benefit of judicial adjustment or academic influence.\(^4\)

Perhaps failure-to-warn doctrine owed its apparent success to the intuitive plausibility of its core assumption. The principle that manufacturers should act to reduce personal injuries by alerting consumers to the relevant risks of product use doubtless struck a responsive chord with almost all judges and academics, the vast majority of whom expressly endorse injury prevention as one of the overriding objectives of the tort system in general and of products liability law in particular.\(^5\)

Perhaps the doctrine enjoyed a long season of immunity from criticism because of the seeming ease with which courts could transpose upon it many of the traditional principles and terms of tort law.\(^6\) In time-


\(^5\) See, e.g., George L. Priest, Modern Tort Law and Its Reform, 22 VAL. U. L. REV. 1, 5 (1987) (“There are two goals of modern tort law that all can agree upon: to reduce the accident rate as much as is practicable, and to provide a sensible and coherent system of compensation insurance for those . . . who suffer product- or service-related accidents.”). For a judicial analogue, see, for example, McCormack v. Hankscraft Co., 278 Minn. 322, 338, 154 N.W.2d 488, 500 (1967) (“In our view, enlarging a manufacturer’s liability to those injured by its products more adequately meets public policy demands to protect consumers from the inevitable risks of bodily harm created by mass production and complex marketing conditions.”).

\(^6\) Professor Schwartz was the first to argue persuasively that, although characterized as a form of “strict” liability, products liability based on warning defects was a form of negligence. See Schwartz, supra note 3, at 462-63; Gary T. Schwartz, The Vitality of Negligence and the Ethics of Strict Liability, 15 GA. L. REV. 963, 972-73 (1981). Most courts have also come to adopt the view that failure-to-warn doctrine sounds in negligence rather than in strict
honored fashion, the methodology of failure-to-warn law focused, for example, on the "foreseeability" of a particular product risk and the "adequacy" of a particular warning label. Judicial reliance on these traditional notions avoided the drastic departures from precedent occasioned both by the application of strict liability rules to cases involving manufacturing defects and by the use of complicated, multi-factor, risk-utility tests for those involving design defects. By requiring manufacturers to provide "reasonable" warnings about "relevant" risks to "average" consumers, warnings doctrine couched its critical terms in the comfortable language of negligence and resembled, at least for a while, a benign and familiar theory, easy to understand and equally easy to apply.

In the past few years, however, as the controversies that plagued the other aspects of products law have abated, the seemingly manageable

liability. Kearl v. Lederle Labs., 172 Cal. App. 3d 812, 218 Cal. Rptr. 453 (1985), contains a representative statement of this view:

As an initial matter we question the commonly assumed and often asserted proposition that in products liability cases failure to warn or inadequacy of warning may be a basis for imposition of strict liability. A review of the cases discloses that the analysis called for in this situation is not based on strict liability, but negligence. . . .

. . . .

Just as liability for failure to warn of product risk is based on negligence, the adequacy of a warning is also judged under a reasonableness standard . . . .

Id. at 831-33, 172 Cal. Rptr. at 466; see also Johnson v. American Cyanamid Co., 239 Kan. 279, 286, 718 P.2d 1318, 1324 (1986) (holding that to impose liability on a manufacturer for failure-to-warn, the plaintiff must show negligence on the part of the manufacturer), aff'd, 243 Kan. 291, 758 P.2d 206 (1988).


8. See discussion supra note 3.

9. See, e.g., Laaperi v. Sears Roebuck & Co., 787 F.2d 726, 731 n.3 (1st Cir. 1986). The first trace of a common-law duty to warn can be found in early Roman sales law, which obligated vendors to disclose hidden product defects of which they actually knew. The strength of this obligation was, no doubt, seriously diluted by the rule that required buyers to prove that their sellers possessed the requisite knowledge of defect. J.A.C. THOMAS, TEXTBOOK OF ROMAN LAW 286-89 (1976). The interplay between modern technology and later incarnations of this early sales-based duty forms the larger background against which this aspect of the revolution in products liability law played itself out. See generally Assault, supra note 1, at 1099-1124 (describing the evolution of strict liability and its extension to consumer plaintiffs); Fall, supra note 1, at 790-813 (continuing study of products liability's expansion begun in Assault).

10. For some impressive statistical indications of a recent reversal of the pro-plaintiff trend which had apparently long characterized judicial decision-making in manufacturing and
doctrine of failure-to-warn has become problematic. After more than
two decades of almost unbroken scholarly silence, in 1988 there
appeared a trickle of mild complaints lamenting the ease with which plain-
tiffs in failure-to-warn cases could successfully establish the necessary
elements of a prima facie case. In the past years, two important works
have contended much more forcefully that serious flaws in failure-to-
warn law have caused the courts to be flooded with claims of faulty prod-
cuct warnings, necessitating reconsideration of the manner in which
courts should apply that law.

Although strongly critical of warnings doctrine in practice, each of
these more recent works implicitly adopts the flawed assumption that
forms the philosophical foundation of the judicial opinions they criticize.
Each assumes that there exists a legally discoverable and correct content
for product warnings, and each advocates the retention of the content-
based approach historically employed by the judiciary to resolve failure-
to-warn claims. Courts and juries, each work argues, should examine
closely the substance of particular warnings and properly distinguish the
"obvious" risks from the "hidden" ones, the "average" consumers from the
"atypical," and the "adequate" warning label formats from the "in-


14. See infra notes 219-26 and accompanying text.
adequate.” If they conduct the “right” kind of examination, using the “correct” definitions and strictly applying the traditional limitations on the abuse of doctrinal discretion, the institutional factfinders will discover the “correct” content for the warning in question, existing analytical problems will abate, the flood of claims will recede, and the law will function effectively. This Article argues that these commentators are mistaken, not only about the nature and gravity of observed doctrinal weaknesses, but more significantly about the type of approach best suited to remedy them.

The flaws in the law of failure-to-warn are much more serious than previously contemplated, so serious indeed that efforts to repair the doctrine along the content-oriented lines suggested by other commentators will not only fail to cure the existing problems but will aggravate them. The important limiting concepts upon which the doctrine relies so heavily for its effective functioning are hollow constructs incapable of assuming useful shape; certain critical terms in the doctrine’s vocabulary are hopelessly devoid of workable meaning. No proposal for reform premised on the substantive reconstruction of those empty concepts or the attempted definition of those amorphous terms can possibly succeed.

The argument elaborated here proceeds from three related perspectives: the descriptive, the prescriptive, and the normative. First, it describes the present state of failure-to-warn law, discussing its fundamental flaws and demonstrating how they have thoroughly stymied the hope of reasoned decision-making. Next, it examines the most recent scholarly suggestions for solving some of the more pressing doctrinal difficulties and contends that all such suggestions, because they concentrate largely on the specific content of particular warnings, are misdirected and, for that reason, ineffectual. Finally, it proposes a procedural solution to the most grievous of the law’s existing shortcomings, an approach intended to harmonize the important informational and safety concerns reflected in warnings theory with the practical impossibility of drafting a product warning perfect in every respect. Arguably, this approach would not only permit courts and juries to apply that body of law in a fair and consistent fashion, but also would offer consumers the prospect of more effective product safety information and would provide manufac-

15. See infra notes 219-26 and accompanying text.

16. For a detailed statistical analysis of the growth in all products liability claims brought in federal court during the years 1977-1987, see W. Kip Viscusi, The Dimensions of the Product Liability Crisis, 20 J. LEGAL STUD. 147, 150-52 (1991) (“[T]here is evidence at the federal court level of a substantial increase in product liability litigation, both in absolute terms as well as in relation to all civil litigation.”).
turers the possibility of producing helpful warning labels that are immune from liability.

II. EXISTING FAILURE-TO-WARN LAW IS EFFECTIVELY DEVOID OF MEANINGFUL STANDARDS

The conventional formulation of failure-to-warn law requires that a manufacturer provide consumers with an adequate warning of the risks associated with the use of its product.\textsuperscript{17} In this sense, warnings doctrine resembles most other well-established legal dogma. It creates a set of discrete obligations defined by a group of critical terms and bounded by certain explicit limitations. Thus, although the untempered logic of the doctrine's basic goal of injury prevention might compel a manufacturer to give every consumer a perfectly drafted warning about every risk associated with product use, the traditional expression of the doctrine modifies that theoretically unbounded set of obligations in a number of significant ways.

First, traditional doctrine relieves manufacturers of the duty to warn about every risk. They need not describe risks that are either "obvious"\textsuperscript{18} to the average consumer or so "remote" that their occurrence is not reasonably foreseeable.\textsuperscript{19} Second, failure-to-warn law does not require manufacturers to fashion product warnings that are ideal in every way. It simply demands that those warnings be "adequate."\textsuperscript{20} Finally, conventional theory does not force manufacturers to anticipate the particular warning needs of every consumer, but permits them instead to direct their product warnings to the attention of the average consumer.\textsuperscript{21}

\begin{itemize}
  \item \textsuperscript{17} See, e.g., cases cited infra note 20.
  \item \textsuperscript{21} See, e.g., Cotton v. Buckeye Gas Prods. Co., 840 F.2d 935, 937-38 (D.C. Cir. 1988); Laaperi, 787 F.2d at 731 n.3; Broussard v. Continental Oil Co., 433 So. 2d 354, 358 (La. Ct.}
The limiting rules pertaining to "obviousness," "remoteness," "adequacy," and the "average consumer" theoretically seek to confine the application of warnings law within bounds that are "reasonable." Restricting the doctrine's scope in this manner would not only strike a useful balance between the perfect and the possible, but would also protect the judicial system from being overwhelmed by an endless flow of cases. At the same time, a legal regime that imposed a set of effective but reasonable requirements would establish for manufacturers a warning task whose parameters are intellectually comprehensible and whose consistent attainment is economically feasible. That, at least, is the theory behind the limiting rules. In practice, however, none of those rules can work because each is ambiguous, subjective, and incapable of reasoned application.

A. The "Obvious Danger" Rule: Indeterminacy in Action

Most jurisdictions embrace the "obvious danger" rule in failure-to-warn cases and require manufacturers to warn consumers about only those product hazards considered hidden or latent. This rule draws support from a variety of sources, all of which share the seemingly plausi-
ble assumption that advising consumers about open and evident product risks is unnecessary or redundant.\textsuperscript{25} Moreover, since space constraints impose limits on the number of warnings that can fit on a particular product, a rule compelling manufacturers to alert consumers to obvious risks might force them to omit mention of other, more subtle risks,\textsuperscript{26} thus weakening the overall efficacy of their warnings.

A minority of jurisdictions\textsuperscript{27} has rejected the obvious danger rule, concluding that the obviousness of a particular risk does not by itself relieve a manufacturer of the duty to warn of that risk.\textsuperscript{28} According to this view, obviousness constitutes but one of a number of factors that manufacturers should consider in drafting “adequate” product warnings.\textsuperscript{29} Since only four jurisdictions adhere to this view, one might expect that the effective sphere of its influence would be narrow, its unusual

\textsuperscript{25} See, e.g., Plante v. Hobart Corp., 771 F.2d 617, 620 (1st Cir. 1985) (“[I]f the law required suppliers to warn of all obvious dangers inherent in a product, ‘[t]he list of foolish practices warned against would be so long, it would fill a volume.’”) (quoting Kerr v. Koemm, 557 F. Supp. 283, 288 n.2 (S.D.N.Y. 1983)).

\textsuperscript{26} But see Broussard v. Continental Oil Co., 433 So. 2d 354, 358 (La. Ct. App.) (specifically discussing “the problems of attempting to put multiple warnings on a hand drill of the size and nature involved”), cert. denied, 440 So.2d 726 (La. 1983); see also Cotton v. Buckeye Gas Prods. Co., 840 F.2d 935, 938 (D.C. Cir. 1988) (similar discussion regarding problems of labeling products).


\textsuperscript{28} The Olson court, for example, premised its rejection of the rule upon the “risk-spreading concept of strict liability,” which it viewed as burdening manufacturers with special legal responsibilities. Olson, 256 N.W.2d at 537. The Horen and Campos courts both found nothing conclusive in the obviousness of a particular risk, but regarded that factor simply as one part of a multi-part test. Horen, 169 Mich. App. at 731, 426 N.W.2d at 796 (stating the test to be “whether the risks are unreasonable in light of the foreseeable injuries”); Campos, 98 N.J. at 207, 485 A.2d at 309 (stating that obviousness of the risk is “one element to be factored into the analysis”). The Harris court was vague about its rationale, incorrectly announcing at one point that the obvious danger doctrine is “seldom used” and stating at another that the doctrine is inconsistent with the “foreseeability concept.” Harris, 640 F.2d at 76.

\textsuperscript{29} See Horen, 169 Mich. App. at 731, 426 N.W.2d at 797; Campos, 98 N.J. at 209, 485 A.2d at 311.
perspective a matter of occasional intellectual curiosity but limited practical significance. It would be wrong, however, to underestimate the probable impact of this particular minority rule, despite the small number of its adherents and whatever theoretical weaknesses might characterize the rationales advanced on its behalf. The four minority jurisdictions (Michigan, New Jersey, West Virginia, and North Dakota) are geographically dispersed, and a manufacturer cannot effectively isolate them from its other markets. Therefore, the manufacturer must inevitably face the risk that some products will find their way into one or more of these jurisdictions, where they will be confronted with a stricter set of warning requirements which cannot safely be ignored. For this reason, even manufacturers doing business exclusively in the so-called majority states must conform their warnings to the minority rule or potentially expose themselves to liability. Thus, as a practical matter, the facts of commercial life extend the minority rule into all jurisdictions and compel every manufacturer to consider obvious risks in its warning label calculus. Whatever benefits the obvious danger rule might confer in the “majority” states that have adopted it are thus likely to be seriously diluted, if not effectively eliminated, by the pervasive influence of this particular minority view.

The universal adoption of the majority position would not, however, cure the problems of the obvious danger rule. Instead, it would serve, as it has in majority jurisdictions, simply to dramatize the hopeless subjectivity of that rule and to reveal its utter inability to perform its theoretical limiting function. The majority rule, made uniform, would still suffer from incurable indeterminacy and would continue to germinate a confusing and irrational assortment of judicial opinions.

Consider, for example, two relatively familiar products: an alcoholic beverage and an above-ground swimming pool. Each presents the average consumer with an array of potential hazards, many of which are seemingly well known: the beverage intoxicates users in a way that might adversely affect their judgment and harm their health; the swimming pool sits on a hard surface, forceful contact with which can cause serious injury. Arguably, these risks should constitute a baseline for the obvious danger rule, the lowest common denominator of its application. In practice, however, when it comes to defining obvious dangers, courts have been unable to agree on a common denominator because their various notions of obviousness have so little in common.

30. My own admittedly anecdotal experience supports this thesis. Along with the hot air corn popper that I recently received came a written warning from the manufacturer telling me: "Do not touch the corn popper when it is hot." THE WEST BEND CO., CARE AND USE INSTRUCTIONS: HOT AIR CORN POPPER 1 (1990).
Even within jurisdictions, different courts disagree about the obviousness of similar risks. In Texas, for example, that state's supreme court held recently that manufacturers of "beverage alcohol" need not warn consumers about the addictive nature of their product, because that danger should be apparent to a reasonable user. Only three years ago, by contrast, a Texas appellate court held that a maker of tequila had a duty to caution consumers that drinking large amounts of its product in a short time could cause death, a prospect deemed not obvious as a matter of law. Courts dealing with above-ground swimming pools generally fare no better. Most refuse to require manufacturers to warn swimmers about the risks of diving into the pool's shallow end; others declare that manufacturers must tell divers, bellyflopers, and users of inner tubes about the hazards posed by forceful bodily contact with the hard bottom of the shallow end of the pool.

These cases are merely illustrative. The world of failure-to-warn is replete with comparable oddities. What this sideshow of strange cases

32. Brune v. Brown Forman Corp., 758 S.W.2d 827, 831 (Tex. Ct. App. 1988). Some argue that McGuire implicitly overrules Brune and demonstrates, finally but definitively, that the Texas jurists have at last recognized the obvious. For example, Professors Henderson and Twerski rejoiced in print over McGuire and heralded its announcement as proof that courts could reach "correct" decisions about the obviousness issue. See Some Obvious Truths About Obvious Danger Warnings, 19 Prod. Safety & Liab. Rep. (BNA) 877, 877 (August 2, 1991) [hereinafter Obvious Danger Warnings]. But a closer look at the genesis of that decision is revealing. The Texas appellate court that decided McGuire ruled unanimously that the risk of alcohol addiction was not obvious and did require a warning. See McGuire v. Joseph E. Seagram & Sons, Inc., 790 S.W.2d 842, 851 (Tex. Ct. App. 1990). Although the Texas Supreme Court took the opposite view, the clearest lesson taught by McGuire is that, for purposes of failure-to-warn law, "obviousness" depends not upon logic, nor upon common sense, nor even upon anything articulate, but rather upon which group of jurists has the final word.
37. Even in Michigan, one of the few states to reject the obvious danger rule, see supra text accompanying note 29, the court of appeals, in a case brought by a 17-year-old plaintiff who had "taken swimming and diving instructions in high school, including a life saving class," found that the risk of diving into shallow water was not open and obvious, because "the risk of serious injury, in this case paraplegia, is not obvious in the absence of some form of warning." Glittenburg, 174 Mich. App. at 326, 435 N.W.2d at 481-82.
38. For example, in Fraust v. Swift & Co., 610 F. Supp. 711 (W.D. Pa. 1985), the plain-
serves strikingly to dramatize is that those courts embracing the obvious danger rule have interpreted it inconsistently, without offering any doctrinally coherent explanation of their views. To the extent that some courts continue to confront directly the problem of distinguishing the “obvious” from the “hidden” risk, it is glaringly apparent that none has articulated a well-reasoned basis for differentiating those terms. As a result, courts have effectively announced that while there might theoretically exist a risk so obvious that manufacturers need not warn about it, as a practical matter they can neither define nor describe that kind of risk. Consequently, they have virtually stripped the obvious danger rule of its limiting function, destroying in practice the boundaries supposed by theory to confine the kinds of risks about which manufacturers must warn.

Though certainly distressing from the perspective of philosophical integrity, from other perspectives the breakdown of the obvious danger rule is not all that startling. “Obviousness” defies objective definition.39

tiff’s 16-month-old son sustained severe injuries when he choked while eating Peter Pan Creamy Peanut Butter, a product made by the defendant. The plaintiff claimed that the peanut butter was unsafe because it lacked a warning that it should not be fed to children under four years of age. Id. at 712. In denying the defendant’s motion for summary judgment, the court held that the risk that a 16-month old might choke on peanut butter was not obvious as a matter of law and that a jury should therefore determine whether the defendant should have warned about that risk. Id. at 714.

The National Law Journal recently reported that a teenage girl filed suit in August 1991 against Nintendo Company and Toys “R” Us, seeking damages for injuries to her wrist that she allegedly incurred by playing Nintendo home video games, and claiming that Nintendo had failed to warn buyers of the physical risks attendant upon the use of its products. See Not Work-Related, NAT’L L.J., Sept. 2, 1991, at 6.

39. In this sense, failure-to-warn law unwittingly serves as a dramatic case study of the theories of critical linguistic scholars. According to these scholars, and to legal realists as well, language in general, and particularly legal language, has no real or fixed meaning. See generally ROBERT M. UNGER, KNOWLEDGE AND POLITICS (1975) (the seminal statement of the critical legal view); Felix S. Cohen, Transcendental Nonsense and the Functional Approach, 35 COLUM. L. REV. 809 (1935) (the classic account of the realist position). James Boyle, who has artfully described the gradual assimilation by critical legal thought of the “post-Wittgensteinian view of language,” summarizes that view as follows:

(1) Words do not have “essences.”
(2) Words do not have “core meanings.”
(3) Language is, or can be, used in an infinite number of ways: it is a malleable instrument of communication.
(4) That a word is most commonly used to mean X does not mean that X is the “core” or “plain” or “essential” meaning of that word. To look to the “plain meaning” of a word as its “real meaning” is a special type of reification, since it ignores the purpose for which the word is actually being used.

Webster's New World Dictionary, for example, defines the word "obvious" as "easy to see or understand," but says nothing about the particular circumstances or people whose characteristics might bear on the ease with which something can be seen or understood. As with "beauty," any understanding of "obvious" must be strictly personal and subject completely to the perspective of the beholder.

The judiciary has demonstrated, much better than semiotic theory ever could, that the word "obvious," by itself and detached from life's contingencies, is inherently ambiguous and utterly subjective, incapable of a more precise definition than Webster's. Thus, to some courts, an obvious product risk is one that is "apparent"; to others, the obviousness of a risk depends upon the plaintiff's "familiarity" with defendant's product; and to others still, obviousness relates to the "essence" of the product. In a manner strangely reminiscent of the French doctor made famous in Felix Cohen's classic simile, every court has fallen unavoidably into the tautological trap of defining an obvious risk as one that is reasonably obvious, a failing foreordained, if not by the indeterminacy of all language, then at least by the insubstantiality of the word "obvious" in this particular context.

necessarily subjective inquiry into the meaning of "intent of parties"); Gerald E. Frug, The Ideology of Bureaucracy in American Law, 97 Harv. L. Rev. 1276, 1287 (1984) (discussing the lack of separate, distinct meaning between the words "subjective" and "objective" and their use in describing the bureaucratic structure in American law); Thomas C. Heller, Structuralism and Critique, 36 Stan. L. Rev. 127, 133-40 (1984) (discussing structuralism and its role in critical legal theory); Mark V. Tushnet, A Note on the Revival of Textualism in Constitutional Law, 58 S. Cal. L. Rev. 683, 695, 700 (1985) (arguing that constitutional textualism fails as a valid theory because it authorizes judges to interpret the law's requirements as "anything from laissez faire to socialism"). A partial bibliography of the literature dealing with modern semantic theory is contained in Boyle's article, supra, at 708-09 nn.77-78.


43. Shaffer v. AMF, Inc., 842 F.2d 893, 898 (6th Cir. 1988) ("The motorcycle's combination of the thrill of the open passenger compartment and the response of the powerful engine in a lightweight frame, . . . is the essence of the motorcycle's dangers.").

44. See Cohen, supra note 39, at 820 ("Legal arguments couched in these terms are necessarily circular, . . . and such arguments add precisely as much to our knowledge as Moliere's physician's discovery that opium puts men to sleep because it contains a dormitive principle.").

45. See supra note 39.
Some commentators think otherwise. In a recent article, for example, Professors Henderson and Twerski discuss the obvious danger rule at length, referring to it as the rule which, "[p]erhaps more than any other aspect of warnings doctrine . . . should help courts cull unworthy failure-to-warn claims from the worthy." Henderson and Twerski argue that the obvious danger rule not only could, but would, serve this salutary purpose, if only courts were to heed their criticisms and adopt some simple suggestions. They contend implicitly that the obviousness of a particular risk is measurable and should be, in each case, a relative matter, dependent upon the particular plaintiff and "the class of users and consumers of which [he] . . . is a member." They criticize courts for making "the largest single error" respecting obviousness, the error of sending too many cases to the jury on weak facts. As an antidote, they urge courts to raise the standard of obviousness and to interpret the obvious danger rule more robustly.

These criticisms seem valid, at least superficially. Their accompanying suggestions have a logical and useful ring to them. Courts should define obviousness correctly and try harder to keep weak cases from the jury. If they do, great progress will follow, and the faltering doctrine of failure-to-warn will at last find itself firmly on solid ground. Sadly, however, for simplicity's sake, the validity of the Henderson-Twerski criticisms, the utility of their suggestions, and the value of their approach all depend entirely upon the heroic assumption that courts can logically arrive at a shared understanding of what constitutes an obvious risk. If that assumption collapses under the weight of fact, if no amount of "robust" effort can lead courts to the one, true definition of obviousness, if courts are compelled by the indeterminacy of the concept to fashion a hodgepodge of mutually inconsistent views, then proposals like those of Professors Henderson and Twerski, though appealing in the abstract, will not work in practice.

If anything is obvious about the obvious danger rule, it is that courts cannot agree on the definition of an "obvious" risk. Joseph E. Seagram & Sons, Inc. v. McGuire provides an instructive example of this phe-

46. Doctrinal Collapse, supra note 13, at 265.
47. Id. at 280.
48. Id. at 285.
49. Id.
50. Id. at 317. Henderson and Twerski also argue that the obvious danger rule makes such good sense that those few courts which have thus far rejected it should change course, accept the rule, and apply it uniformly and without exception. Id. at 280-82.
51. 814 S.W.2d 385 (Tex. 1991); see supra note 31 and accompanying text.
nomenon. Plaintiffs\textsuperscript{52} in \textit{McGuire} alleged that they suffered from alcoholism caused by their consumption of beverages manufactured and sold by Seagram and another defendant,\textsuperscript{53} and that those beverages were defective and unreasonably dangerous because they were distributed without a warning of the addictive nature of beverage alcohol.\textsuperscript{54} Seagram moved at trial to dismiss the complaint on the grounds that "the effects of beverage alcohol are commonly known" and that it had no duty to warn the consumer about common knowledge.\textsuperscript{55} The trial court granted Seagram's motion.\textsuperscript{56} The court of appeals reversed, and the Texas Supreme Court reversed again, reinstating the original order of dismissal, on the ground that Seagram had no duty to warn since these were obvious risks.\textsuperscript{57}

Professors Henderson and Twerski applauded the final decision in \textit{McGuire}.\textsuperscript{58} To them, it represented a perfect example of their theories at work; like several other appellate courts,\textsuperscript{59} the Texas Supreme Court properly recognized the obvious risks attendant upon the prolonged or excessive consumption of alcohol, correctly decided that the manufacturer need not warn about them, and appropriately removed the case from the system before it could get to the jury.\textsuperscript{60}

\textit{McGuire}, however, refutes rather than supports the Henderson-Twerski thesis and demonstrates dramatically why a legal doctrine dependent upon characterizing particular risks as "obvious" or "hidden" is destined to fail. While the justices of the Texas Supreme Court saw the product risks in \textit{McGuire} as obvious, at least two of the appellate court judges did not.\textsuperscript{61} Though the supreme court's decision in \textit{McGuire} ac-

\textsuperscript{52} There were several plaintiffs in \textit{McGuire}; three separate actions had been consolidated for appeal. See \textit{McGuire v. Joseph E. Seagram \& Sons, Inc.}, 790 S.W.2d 842, 844 (Tex. Ct. App. 1990), \textit{rev'd}, 814 S.W.2d 385 (1991).

\textsuperscript{53} Id. The other named defendant was Hiram Walker Inc.

\textsuperscript{54} Id. at 846.

\textsuperscript{55} Id.

\textsuperscript{56} Id. at 853.

\textsuperscript{57} Joseph E. Seagram \& Sons, Inc. v. McGuire, 814 S.W.2d 385, 388 (Tex. 1991).

\textsuperscript{58} See \textit{Obvious Danger Warnings, supra} note 32, at 877. Professors Henderson and Twerski helped to prepare an amicus brief urging reversal of the appellate court's decision. \textit{Id}.

\textsuperscript{59} See \textit{Garrison v. Heublein, Inc.}, 673 F.2d 189, 192 (7th Cir. 1982); \textit{Maguire v. Pabst Brewing Co.}, 387 N.W.2d 565, 569-70 (Iowa 1986); \textit{Pemberton v. American Distilled Spirits Co.}, 664 S.W.2d 690, 693 (Tenn. 1984).

\textsuperscript{60} \textit{Obvious Danger Warnings, supra} note 32, at 881.

\textsuperscript{61} Chief Justice Walker wrote a separate concurrence agreeing that "these cases in all things be reversed." \textit{McGuire v. Joseph E. Seagram \& Sons, Inc.}, 790 S.W.2d 842, 854 (Tex. Ct. App. 1990) (Walker, C.J., concurring), \textit{rev'd}, 814 S.W.2d 385 (1991). In 1988, a different panel of the Texas Court of Appeals split, two to one, over the issue of whether the maker of Miller Lite beer should have warned consumers about the dangers of driving an automobile after excessive beer consumption and instructed them on the safe use of its product. While the
cords with those of most other appeals courts that have considered the issue, it conflicts with others. In Hon v. Stroh Brewery Co., for example, the Third Circuit rejected the obvious danger defense and accepted plaintiff’s claim that a warning may have been required on defendant’s beer cans because it was not common knowledge that “either excessive or prolonged, even though moderate, use of alcohol may result in diseases of many kinds.”

If, as Henderson and Twerski contend, obvious risks are simply waiting there for courts to recognize, then what accounts for the sharp disagreement between the appeals court judges and the supreme court justices in McGuire? What explains the drastically dissimilar views of the Third and Seventh Circuits, for instance, about the obviousness of the risks of prolonged or excessive consumption of alcohol? Moreover, what justifies the pervasive and continuing inability of the judiciary to define “obviousness” in objective terms? Henderson and Twerski describe as “absurd” a number of cases involving “patently obvious dangers” that courts have nevertheless refused to dismiss. They inform us

majority held that the risks were obvious and the instruction unnecessary, Chief Justice Evans argued in dissent that plaintiff should have been allowed to take to the jury her allegation that Miller “could have issued safety instructions to its consumers about how much Miller Lite Beer a person could safely consume before becoming too inebriated to drive.” Malek v. Miller Brewing Co., 749 S.W.2d 521, 525 (Tex. Ct. App. 1988) (Evans, C.J., dissenting).

62. See cases cited supra note 59.

63. McGuire conflicts not only with Hon, discussed infra notes 64-65 and accompanying text, but interestingly enough also with Brune v. Brown Forman Corp., 758 S.W.2d 827 (Tex. Ct. App. 1988), where a different panel of the Texas Court of Appeals held that a complaint, alleging that tequila was not safe for its intended use without instructions describing how to use it safely, raised a genuine issue of material fact. Id. at 831.

64. 835 F.2d 510 (3d Cir. 1987).

65. Id. at 511. Professors Henderson and Twerski dismiss Hon as irrelevant to the “core risks at the heart of the obvious danger rule,” contending that it involved only a claim that consumers were unaware “of the risks arising from non-excessive drinking.” See Obvious Danger Warnings, supra note 32, at 881. The passage from Hon quoted in the text, however, casts some doubt on that contention. More significantly, even if the issue in Hon is properly described as whether a manufacturer of alcohol must warn consumers about the risks of prolonged but moderate alcohol use, the likelihood that courts and juries will agree unanimously about the obviousness of those risks seems slim.

66. Compare Garrison v. Heublein, Inc., 673 F.2d 189, 192 (7th Cir. 1982) (warning not required about the harmful “propensities” of alcohol because “the dangers of the use of alcohol are common knowledge to such an extent that the product cannot objectively be considered to be unreasonably dangerous”) with Hon, 835 F.2d at 511 (finding no such common knowledge). The danger of addiction to alcoholic beverages, however, which may not be so well-known, might necessitate a specific warning, even in those jurisdictions that have characterized the behavior-altering quality of alcohol as common knowledge. See, e.g., Alan Schwartz, Views of Addiction and the Duty to Warn, 75 VA. L. REV. 509, 511 (1989) (discussing the lack of warnings regarding the addictions that may result from drug and alcohol use).

67. See supra text accompanying notes 38-44.

68. See cases collected in Doctrinal Collapse, supra note 13, at 317 nn.208-12.
that these cases "are not isolated examples" and that the reporters "abound with them." They fail to recognize, however, that these large numbers of what they call "absurd" results follow inevitably from the inherent impossibility of uniformly applying an obvious danger rule, the features of which are hopelessly indistinct.

Courts and commentators are certainly not to blame for having failed to recognize or develop a universally acceptable definition of "obviousness." Rather, it seems clear that no acceptable definition can possibly exist. In specific cases reasonable judges will always disagree, easily and rationally, about the application of the obvious danger rule to particular risks; honesty but differing notions of semantics, common sense, and intuition will inevitably lead courts and commentators alike into these kinds of disagreements. Obviousness is either an empty concept or an indeterminate one, but in no event can it help to resolve any but the simplest of failure-to-warn cases. The obvious danger rule simply does not work.

B. The Remote Danger Rule

If the obvious danger rule is theoretically supposed to stabilize one end of warnings doctrine, then the remote danger rule is meant to anchor the other. Traditionally, the remote danger rule excuses the manufacturer from any duty "to warn of a risk that is remotely possible to the unknown few in the population." As the apparent complement to its

69. Id. at 317.
70. Problems of semantic subjectivity are not, of course, unique to failure-to-warn law. Discussing the provision of § 520 of the Restatement (Second) of Torts that defines "abnormally dangerous activities" partly in terms of the social value of the particular activity, the Supreme Court of Oregon observed:

There are at least two reasons not to judge civil liability for unintended harm by a court's views of the utility or value of the harmful activity. One reason lies in the nature of the judgment. Utility and value are often subjective and controversial. They will be judged differently by those who profit from an activity and those who are endangered by it, and between one locality and another . . . . Judges, like others, may differ about such values; they can hardly be described as conclusions of law.


71. This is neither a logically nor a linguistically symmetrical phenomenon. "Remote" and "obvious" are not antonyms. The opposite of remote is "near" or "likely," while the opposite of "obvious" is "hidden." Remoteness, moreover, is a probabilistic notion, while "obviousness" is not.

obviousness counterpart, the remote danger rule serves an analogous limiting purpose, attempting to keep from the jury a second category of cases involving risks for which warnings are thought unnecessary, and thus to restrict the world of actionable warnings cases to those involving risks hidden from the consumer but reasonably foreseeable to the prudent manufacturer.

In application, unfortunately, the remote danger rule does very little to circumscribe failure-to-warn doctrine. The definitional problems that plague judicial efforts to give precise and broadly applicable meaning to the term "remote" seem almost as acute as those attendant upon attempts to develop a working definition of "obvious." This difficulty exists largely because the remote danger rule is probabilistic in nature; in order to apply it effectively, courts must complete two essentially impossible tasks. They must first either locate or compile valid statistical measures that accurately describe the frequency with which a particular risk will cause harm. Second, they must translate those measures into a relatively precise and generally acceptable legal notion of remoteness.

Courts have thus far made almost no progress toward accomplishing either of those tasks. For most products, no risk-based statistics exist. For this reason, except in cases involving adverse reactions to pharmaceutical or chemical products, judicial opinions discussing the

73. Webster's Dictionary defines "remote" as: "1. [D]istant in space or time; . . . [D]istant in connection, relation . . . ; [3] [s]light; [a remote chance]." WEBSTER'S NEW WORLD DICTIONARY OF AMERICAN ENGLISH, supra note 40, at 1135.

74. Professors Henderson and Twerski, for example, note that "the remoteness of the perceived risk will rarely provide the court in a failure-to-warn case with an independent means of taking the plaintiff's claim from the jury;" they claim that courts apply the obvious danger rule to limit manufacturer liability much more often than they use the remoteness rule for that end. Doctrinal Collapse, supra note 13, at 294.

75. Ideally, product warnings would accomplish two related ends: They would not only inform consumers of the frequency of a particular risk, but would also alert them to the probable severity of harm associated with the occurrence of that risk. See Schwartz, supra note 12, at 396. To resolve the remoteness question with the proper degree of precision, courts must be able to decide rationally and with some degree of uniformity that, for example, a risk of death (or serious personal injury, or injury of any kind) is legally remote with respect to product x (or with respect to all products, or to only those products that are of the same "type" as product x) at the probability level of, say, one in a million.

76. In the pharmaceutical field, manufacturer-supplied data allowed a number of courts to apply the remote danger rule in an apparently rational fashion in cases involving claims of failure-to-warn for allergic or adverse drug reactions. See, e.g., Blalock v. Westwood Pharmaceuticals, Inc., No. 89-2117, 1990 U.S. Dist. LEXIS 974, at *4 (E.D. La. Jan. 30, 1990) (one million units of sunscreen sold; one complaint); Lemoine v. Aero-Mist, Inc., 539 So. 2d 712, 714 (La. Ct. App. 1989) (citing expert physician testimony that chemicals in insecticide caused allergic reaction in only one of 30,000 allergic patients examined by him); Booker v. Revlon Realistic Professional Prods., Inc., 433 So. 2d 407, 410 (La. Ct. App. 1983) (seven million potential users; four complaints received); Rhodes v. Max Factor, Inc., 264 So. 2d 263, 267 n.7 (La. Ct. App. 1972) (1.25 million units sold; 65 complaints); Thomas v. Gillette Co.,
remoteness of a particular risk rarely refer to any data whatsoever, but rely instead upon anecdotal evidence and intuition. In only a small minority of cases do courts expressly rely on statistical measures of probability, and in many of those cases the validity and objectivity of the statistical measures are questionable. In those few cases where they do possess "good" data, courts sometimes require manufacturers to warn about risks that pose a statistically insignificant possibility of injury, without advancing a logical rationale for such a requirement. Moreover, since courts rarely have any useful data at their disposal, they necessarily treat the concept of remoteness in vague and idiosyncratic ways, occasionally making the duty to warn a function not just of foreseeability.

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77. See, e.g., Elsroth v. Johnson & Johnson, 700 F. Supp. 151, 162 (S.D.N.Y. 1988) (characterizing drug tampering as a remote danger because it stems from "isolated incidents of . . . crazed behavior").

78. In this context, a court's intuitive understanding about the remoteness of a particular risk must necessarily be deeply influenced by the fact that the risk in question has materialized and caused serious harm to the plaintiff before it. Thus, the formation of judicial intuition inevitably begins with the judge's personal knowledge that the arguably "remote" risk has resulted in a case of actual harm.

79. See cases cited supra note 72.

80. In all of the pharmaceutical and chemical products cases collected at supra note 76, both components of the probability data used by the courts were generated exclusively by the manufacturer-defendants. The manufacturer's figures on sales constitute the denominator of the probability fraction; its figures on product-related injuries comprise the numerator. Moreover, the fact that the numerator represents only those injuries reported by consumers to the manufacturer, and not all injuries, casts further doubt on the validity of the kind of data customarily used in those cases.

81. Recently, for example, in Ayers v. Johnson & Johnson Baby Prods. Co., 59 Wash. App. 287, 797 P.2d 527, aff'd, 11 Wash. 2d 747, 818 P.2d 133 (1990), a Washington State appellate court reinstated a jury verdict for the plaintiffs in the amount of $2,500,000, holding in the process that the defendant, the manufacturer of its own brand of baby oil, should have placed a warning on its product alerting buyers to the risks posed by aspiration of the bottle's contents. Id. at 296, 797 P.2d at 533. Given that from 1932 to 1985, the year of the injury at issue, "Johnson & Johnson had sold over 500 million bottles of baby oil without a single report of aspiration," the dissent regarded the risk of aspiration as "exceedingly remote." Id. at 297-98, 797 P.2d at 533 (Reed, J., dissenting). The applicable warnings provision of the Washington Products Liability Act seemed specifically to make foreseeability one of the legally relevant criteria in failure-to-warn cases by directing courts to consider "the likelihood that the product would cause [plaintiff's] harm." WASH. REV. CODE ANN. § 7.72.030(1)(b) (West 1992). The majority, however, paid no heed either to the statistical information or to the apparent foreseeability requirement, declaring that in failure-to-warn actions the foreseeability of injury is not an element of the claim. *Ayers,* 59 Wash. App. at 295, 797 P.2d at 531.
of harm but of severity of harm as well.\(^{82}\) Without objective and empirical measures of probability, courts thus are condemned to apply the remote danger rule in the same vague and confusing fashion that characterizes their application of the obvious danger standard.\(^{83}\)

The remote danger rule poses other significant practical problems. First, because judges see plaintiffs actually injured by the realization of arguably "remote" risks, many might be inclined to feel sympathy for the casualties of such risks, to conclude that the addition of one more simple sentence to the defendant's warning label would have prevented the plaintiff's injury, and to find on that basis that the defendant's product should have contained a more complete warning.\(^{84}\) The application of this judicial philosophy leads inexorably to the piecemeal and uncontrolled expansion of the content of warning labels, without any broad consideration first being given to the problems of informational overload\(^{85}\) and consumer confusion\(^{86}\) that may attend overly elaborate warning messages.

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82. See, e.g., Butler v. L. Sonneborn Sons, Inc., 296 F.2d 623, 626 (2d Cir. 1961) ("When injury is likely to be serious . . . even slight foreseeability may warrant . . . a conclusion . . . that prudence requires the manufacturer to take on [the] small added burden" to warn.).

83. See Tremblay v. Jewel Cos., 859 F.2d 517, 523 (7th Cir. 1988) (warning unnecessary where plaintiff's harm "not reasonably foreseeable" or risk is "remotely possible to the unknown few in the population").

84. See Doctrinal Collapse, supra note 13, at 293-94. These criticisms are certainly valid, but they seem secondary to what one should consider the main problem: the extreme difficulty of providing the concept of "remoteness" with sufficient statistical or semantic clarity to enable courts to decide like cases in a like manner and to inform manufacturers in advance of trial of those risks that must be described in their warning labels.

85. The scientific literature describes information overload as a process of informational exchange by which, providing large amounts of information to consumers, results in their making objectively poorer decisions. See James R. Bettman et al., Cognitive Considerations in Designing Effective Labels for Presenting Risk Information, 5 J. MARKETING & PUB. POL'Y 1, 7 (1986); Naresh K. Malhotra, Information Load and Consumer Decision Making, 8 J. CONSUMER RES. 419, 427 (1982). Bettman, Payne, and Staelin state that because of the overload phenomenon, "an important issue in the design of product labels is to present sufficient information for informed choices without presenting so much information that consumers will process it selectively, possibly leading to suboptimal choices." Id. The empirical evidence supporting the overload hypothesis is equivocal, and the validity of the hypothesis itself is the subject of much debate in the scientific and legal literature. See infra note 91 and accompanying text.

86. Professors Twerski, Weinstein, Donaher, and Pichler were the first legal scholars to argue that the continual addition of risk information to product warning labels might entail costs unanticipated by courts employing a risk-utility balancing test. In particular, they argued that warnings must call the consumer's attention to a danger that has a real probability of occurring and whose impact will be significant . . . . The warning process, in order to have impact, will have to select carefully the items which are to become part of the consumer's mental apparatus while using the product. Making the consumer account
Finally, a distinct minority of courts refuses to accept the basic principle that manufacturers need not warn about remote risks. For these courts, no risk is too improbable to excuse a manufacturer's failure to warn of it, even a risk unknowable to the manufacturer at the time that its product is sold.\textsuperscript{87} Judicial adherents of this extreme approach have expanded the manufacturer's duty to warn so dramatically as to alter the nature of the relevant legal inquiry. In states that reject the remoteness rule, a product warning "perfect" in all reasonable respects could nevertheless become the basis for manufacturer liability should a consumer injury eventuate from a product hazard that was not only unforeseeable to the manufacturer but was neither known by, nor knowable to, anyone in the world.\textsuperscript{88} Critics of this approach have correctly condemned it as both unfair and inefficient.\textsuperscript{89} But it stands there, nevertheless, at one of the far ends of failure-to-warn doctrine, imposing upon manufacturers requirements that cannot possibly be met.

\textsuperscript{87} Following the lead of the New Jersey Supreme Court in Beshada v. Johns-Manville Prods. Corp., 90 N.J. 191, 204-08, 447 A.2d 539, 546-47 (1982), which rejected the "state of the art" defense in products liability cases, a number of other courts adopted a strict liability standard for scientifically unknowable risks. See, e.g., Kisor v. Johns Manville Corp., 783 F.2d 1337, 1341 (9th Cir. 1986) (applying Washington law and holding that manufacturer's ignorance of risks will not alleviate liability); In re Hawaii Fed. Asbestos Cases, 699 F. Supp. 233, 236 (D. Haw. 1988) (applying Hawaii law and rejecting "state-of-the-art evidence" as a defense in failure-to-warn cases); Hayes v. Ariens Co., 391 Mass. 407, 413, 462 N.E.2d 273, 277 (1984) (attributing knowledge of product risks to vendor regardless of his actual knowledge of those dangers); Elmore v. Owens-Illinois, Inc., 673 S.W.2d 434, 438 (Mo. 1984) (holding that manufacturer's standard of care is irrelevant); Carrecter v. Colson Equip. Co., 346 Pa. Super. 95, 104, 499 A.2d 326, 331 (1985) (holding manufacturer liable for all risks regardless of knowledge). Two years after its decision in Beshada, the New Jersey Supreme Court limited the rule announced in Beshada to asbestos cases only, declaring for other types of cases a rule that requires that defendants prove that the risk information in question "was not reasonably available or obtainable and that [they] therefore lacked actual or constructive knowledge of the defect." Feldman v. Lederle Lab., 97 N.J. 429, 455, 479 A.2d 374, 388 (1984). The other jurisdictions that followed New Jersey's lead in Beshada have not joined in its subsequent partial retreat from the strict liability rule formulated in that case.

\textsuperscript{88} Like the minority position on the obvious danger rule, see supra notes 27-29 and accompanying text, the minority view of remote risks is likely to have a disproportionately broad practical influence.

\textsuperscript{89} See supra note 4 and accompanying text; see also Doctrinal Collapse, supra note 13, at 273-75. The difficulties of insuring oneself efficiently against the occurrence of an unknowable risk are larger than, but not too different from, those created by the remote danger rule's requirement that a manufacturer explore all conceivable possibilities of harm in order to determine which, if any, should be described in its warning. The problem of deciding on the efficient amount to invest in discovering the boundaries of remote risk appears almost as acute as the problem of knowing how much to invest in attempting to find the unknowable.
C. Judicial Alternatives to Traditional Doctrine: Right Question, Wrong Answer

Most courts fail even to acknowledge the doctrinal dead-end resulting from the disintegration of the obvious and remote danger rules and the consequent irresistible movement toward a warning requirement fully comprehensive as to risk. Two courts, however, have expressly recognized smaller problems within this larger dilemma and have sought to address them directly.90 These courts have realized that a legal obligation to warn about virtually every risk cannot be translated pragmatically into a regime of completely comprehensive warning labels. For many products, the relatively small size of the product itself effectively limits the physical space available for warning information. For those products, courts have acknowledged that practical wisdom might dictate warning labels that are less than exhaustive, since many consumers either might be incapable of understanding and remembering extensive information about risk or might be inhibited from reading a cluttered or complicated warning label.91


91. See discussion of overload, supra notes 85-86. The United States Supreme Court, for example, has stated that "meaningful disclosure does not mean more disclosure. Rather, it describes a balance between competing considerations of complete disclosure . . . and the need to avoid . . . informational overload" . . . And striking the appropriate balance is an empirical process that entails investigation into consumer psychology." Ford Motor Credit Co. v. Milhollin, 444 U.S. 555, 568 (1980) (citations omitted); see also cases cited supra note 76 (noting that, in the pharmaceutical field, manufacturer supplied data allowed courts to apply the remote danger rule in an apparently rational fashion); Robert W. Shuy, Warning Labels: Language, Law, and Comprehensibility, AMERICAN SPEECH 65, 300 (1990) ("It is often said that some half of all American readers cannot process sentences over 13 words long. Obviously, a manufacturer concerned about communicating a danger message would make the sentences shorter than 13 words in order to make the Warning section as readable as possible.").

In the legal and psychological literature, however, an active debate exists about the scientific merits of the information overload hypothesis. Compare, e.g., David Grether et al., The Irrelevance of Information Overload: An Analysis of Search and Disclosure, 59 S. CAL. L. REV. 277, 294 (1986) ("[T]he best inference from the evidence is that consumers do not experience serious problems as a result of the amount of information that markets and the state now generate.") with Schwartz & Driver, supra note 11, at 59 ("The possibility of overwarning is an important limitation on the length and comprehensiveness of a product warning . . . . A warn-
The two courts that have directly confronted the problems of space constraint and warning complexity have been unsuccessful in devising workable solutions for them. In *Broussard v. Continental Oil Co.*, a Louisiana appellate court held that Black & Decker, one of the defendants, was not required to place any specific warnings on its electric hand drill, since the face of the drill cautioned users to consult the owner's manual, which explicitly described the relevant risks. The court acknowledged both the physical impossibility of placing "multiple warnings on a hand drill of the size and nature involved" and the distinct likelihood that a "consumer would have a tendency to read none of the warnings if the surface of the drill became cluttered with [them]."

In *Cotton v. Buckeye Gas Products Co.*, the United States Court of Appeals for the District of Columbia reached the same conclusion about the wisdom of demanding an overly inclusive warning label on a propane gas cylinder.

Together, these courts took an important first step toward a more functional approach to warnings law by recognizing that the implementation of a comprehensive risk rule for product warnings inevitably must collide with the constraints of physical space. Neither court, however, accompanied its keen practical insight with any rule of decision that might rationalize warnings law. Instead, by creating yet another set of tenuous legal distinctions, the opinions serve to muddy already murky waters. Thus, in response to the problems caused by the practical limits on label space, the *Broussard* court first created a distinction between

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93. 840 F.2d 935 (D.C. Cir. 1988).
94. Id. at 358.
95. Id. at 938 ("The inclusion of each extra item dilutes the punch of every other item. Given short attention spans, items crowd each other out; they get lost in fine print.").
“small” products and “large” products, and then held that specific risk information need not appear on “small” products, provided they contain a statement directing users to a comprehensive owner’s manual. “Large” products presumably would have to display on their surfaces the same kind of extensive risk information that should be included in an adequate owner’s manual. A manufacturer’s warning obligations would thus depend in part upon the size of its product, a criterion of questionable utility, and in part upon the existence of a comprehensive owner’s manual, an equally problematic factor.

Moreover, while both the Cotton and Broussard courts criticized lengthy warning labels as potentially confusing or discouraging to consumers, neither court seemed to think that an equally lengthy owner’s manual might present consumers with the same prospect of confusion or discouragement. Both courts appeared to encourage the makers of “small” products to substitute a complicated owner’s manual for a comprehensive warning label, but neither court offered any explanation of how that substitution would meet the informational needs of consumers or of how it would avoid the kind of “overload” that each decried. Consequently, although the Broussard and Cotton cases are unique in directly acknowledging some of the difficulties implicit in warning rules that unduly expand the concept of relevant risk, each fails to furnish that concept with workable meaning or to propose any useful alternative or corollary to it.

In my opinion, no useful alternative exists. The occasional at-
tempts, like those in *Broussard* and *Cotton*, to rescue the doctrine from itself by adjusting the scope of the warning requirement to fit the size of the product, serve to illuminate the serious flaws in the doctrine but do nothing to eliminate those flaws or to buffer their ill effects.

III. THE EXISTING APPROACH TO THE "ADEQUACY" REQUIREMENT OF FAILURE-TO-WARN LAW

The dilemma created by the erosion of the rules of obvious and remote danger, and by the practical impossibility of placing meaningful limits on the notion of relevant risk, might by itself warrant a fundamental rethinking of failure-to-warn law. As significant and troubling as it is, however, that dilemma is not the only serious problem afflicting warnings law. Even if courts could somehow succeed in delimiting the concept of risk, they still would need to solve the problem of elaborating the broad doctrinal requirement that product warnings be "adequate."

Failure-to-warn law now obligates manufacturers not only to warn consumers about relevant risks, but to do so in a manner deemed adequate as to content, format, and audience.\(^{101}\) And unlike the issue of "risk"—which courts have decided can be taken from the jury at the obvious and remote ends of the spectrum—the issue of "adequacy" is one peculiarly for the jury's determination.\(^{102}\) As they have with the notion of risk, courts have struggled in vain with the adequacy requirement, trying to bring solid legal form to a hopelessly malleable set of concepts.\(^{103}\) In the process, they have proved that constructing a workable notion of an "adequate" warning is at least as difficult a judicial task as limiting the concept of "relevant" risk.\(^{104}\)

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103. Compare, e.g., *Burch v. Amsterdam Corp.*, 366 A.2d 1079, 1087 (D.C. 1976) *with* *Murray v. Wilson Oak Flooring Co.*, 475 F.2d 129, 132 (7th Cir. 1973). These two cases involved the adequacy of a warning about the risks of a contact adhesive that seriously injured plaintiffs when it ignited while being applied in the home. In the former, the appellate court held that the warning, "Danger! Extremely Flammable ... Do Not Use Near Fire or Flame," was not adequate as a matter of law, *Burch*, 366 A.2d at 1087; in the latter, the trial court found a similar warning adequate as a matter of law. *Murray*, 475 F.2d at 132.

104. Professor Schwartz has described the "adequacy" dilemma by attributing to the "unavoidable imprecision of a firm's communications about risk levels" the fact that, from a post-injury perspective, "there always exists a warning ... that [was] not given and that would have induced the injured consumer to avoid injury." Schwartz, supra note 12, at 397. According to Schwartz, this circumstance helps explain why "warning cases often permit contradictory outcomes: either the warning ... may be found exculpatory because the firm said enough ... or
To appreciate the complexities entailed in defining an "adequate" warning, consider the various ways in which current legal doctrine tests a particular warning for adequacy. The general rule holds that an adequate warning is one that is reasonable under the circumstances. Courts have, however, divided this broad rule into a number of more specific subparts. Thus, a product warning must be adequate with respect to the content of its message; that is, it must provide the consumer with information about the "right" number of risks ("numerical adequacy"). It must be adequate with respect to the format of its message ("stylistic adequacy"); risk information must be designed to attract the consumer's attention and expressed in a manner that not only is intelligible to the average consumer but also expresses accurately the nature and severity of the risks described. It must also be adequate as to the particular consumer, properly taking into account the consumer's expertise or lack thereof ("experiential adequacy") and his or her language and literacy level ("linguistic adequacy").

A. In Practice, the Numerical Adequacy Rule Serves No Limiting Function

In theory, the numerical adequacy rule could serve to ameliorate some of the problems occasioned by the inevitably limitless nature of the content-based approach to risk. One could imagine, for example, an adequacy requirement that would continue to view almost all risk as relevant, but that would admit the impossibility of successfully warning about every relevant risk, and that would therefore regard as legally ade-


107. See, e.g., Stapleton v. Kawasaki Heavy Indus., Ltd., 608 F.2d 571, 573 (5th Cir. 1979); Dalton v. Tulane Toyota, Inc., 526 F. Supp. 575, 579 (E.D. La. 1981). One of the most complete statements of this obligation appears in D'Arienzo v. Clairol, Inc., 125 N.J. Super. 234, 310 A.2d 106 (1973), where the court stated that whether a warning adequately makes the user aware of a product's dangers and their severity "depends upon the language used and the impression that it is calculated to make upon the mind of the average user of the product" and involves "questions of display, syntax and emphasis." Id. at 230-31, 310 A.2d at 112.


quate a warning describing the five or ten “most important” product hazards. The promise of that theory, however, is frustrated by judicial practice.

As applied, the rule of numerical adequacy places no constraints on the open-ended concept of risk. Most courts effectively ignore the limiting potential of the rule. They choose instead to resolve the question of numerical sufficiency by the same kind of risk-utility analysis ordinarily employed in design defect cases, ultimately reaching the foregone conclusion that manufacturers should expand the content of their warning labels to include the additional message sought by plaintiffs. For these courts, an inadequate warning label is one that could have been made more comprehensive at relatively low cost, cost being regarded exclusively as the number of dollars needed for the manufacturer to tack another line or two of script onto its existing warning label. Confronted with an injured plaintiff, a risk that has materialized, and a warning that did not describe that risk, those courts decide easily and often that the addition of a few words to the manufacturer’s warning label would have cost very little and would have prevented the plaintiff’s expensive injury, and that therefore the warning label was legally inadequate.

110. For a description of conventional risk-utility analysis and its method of application in design defect cases, see supra notes 3, 7 and accompanying text.

111. For a classic statement of this approach, see Moran v. Faberge, Inc., 273 Md. 538, 332 A.2d 11 (1975), in which the court stated:

We observe that in cases such as this the cost of giving an adequate warning is usually so minimal, amounting only to the expense of adding some more printing to a label, that this balancing process will almost always weigh in favor of an obligation to warn of latent dangers, if the manufacturer is otherwise required to do so.

Id. at 543-44, 332 A.2d at 15; see also cases cited supra note 105 (noting the general rule that an adequate warning is one that is reasonable under the circumstances). In computing their calculations of cost, the Moran court and others like it neglect to consider how the additional line or two of printing that they would require might itself generate important non-monetary costs, such as the losses in consumer satisfaction and in manufacturer profitability attributable to product sales foregone because of confusing or intimidating warnings, and the loss of consumer comprehension occasioned by warning label “overload.” When one also factors in the possibility that a second court, or a third, might require that additional pieces of hazard information be grafted onto the newly enlarged warning label, the developing picture of non-monetary costs looks quite substantial. See, e.g., Alvin S. Weinstein et al., Products Liability and the Reasonably Safe Product 62-64 (1978); Schwartz & Driver, supra note 11, at 59. Perhaps courts overlook these non-monetary costs because they can not readily quantify them, because they reject the “overload” phenomenon, or because the costs themselves seem speculative.

112. Courts may also decide that juries could properly make such a finding. See, e.g., Ross Lab. v. Thies, 725 P.2d 1076, 1079 (Alaska 1986) (“The cost of giving an adequate warning is usually so minimal, i.e., the expense of adding more printing to a label, that the balance must always be struck in favor of the obligation to warn.”); Freund v. Cellofilm Properties, Inc., 87 N.J. 229, 238 n.1, 432 A.2d 925, 930 n.1 (1981) (“Imposing the requirements of a proper warning will seldom detract from the utility of the product.”); Ayers v. Johnson & Johnson
B. Stylistic Adequacy: The Esoteric Tradition of Scholarship Revived

Most courts analyze questions of stylistic adequacy with the same risk-utility calculus that they apply to issues of numerical sufficiency. Changes in warning label format are almost always regarded as useful for consumers and inexpensive for manufacturers. While issues of numerical adequacy, however, have a relatively confined field of inquiry—should the warning have mentioned one more risk—issues of stylistic adequacy provide an almost boundless area for possible judicial criticism. In addition to the garden varieties of potential format-related insufficiencies, such as the clarity, urgency, or attention-getting quality of a particular warning, courts have catalogued an impressive and bewildering assortment of possible deficiencies. For example, courts have found a warning inadequate as to format because it was located too far back in the product's owner's manual, because the size of its type was too small, because it appeared in an instructional booklet for the product instead of separately in a warning label, and because it failed to provide specific instructions for using the product safely.

Taken together, this enormous assortment of potential inadequacies


113. In Givens v. Lederle, 556 F.2d 1341 (5th Cir. 1977), for example, the court found there to be a meaningful difference between telling users of the Sabin oral polio vaccine that they rarely could contract the disease from the vaccine, which is what the warning stated, and telling them that they could contract the disease from the vaccine, the warning sought by plaintiff. Id. at 1345. The risk of getting polio from the vaccine was one in three million. Id. at 1343. In Michael v. Warner/Chilcott, 91 N.M. 651, 579 P.2d 183 (1978), the court upheld a jury finding of inadequacy of a warning that instructed users not to take sinus medicine for more than ten days without consulting a physician because extended use "may damage the kidneys." Id. at 652, 579 P.2d at 184. The plaintiff used the medicine for eight years without consulting a physician. Id. at 652-53, 579 P.2d at 184-85. The court held that the warning should also have said that the drug was "dangerous." Id. at 655, 579 P.2d at 187.


117. See, e.g., Stapleton v. Kawasaki Heavy Indus., Ltd., 608 F.2d 571, 573 (5th Cir. 1979) (holding that jury could properly have found warning inadequate because it was placed on page 13 of owner's manual, instead of on an earlier page).


furnishes courts with an arsenal of critical weaponry capable of crippling even the most carefully crafted product warning. By scrutinizing closely the seemingly trivial details of type size, warning location, and relative degree of expressed urgency, and by permitting outcomes to hinge on the presence or absence of one or two seemingly innocuous words, courts impose upon manufacturers a duty of virtual perfection, easily breached, and satisfied only by chance.\footnote{121}

\textbf{C. The "Average Consumer" and the Increasingly Common Non-Average Consumer}

In failure-to-warn law, the concept of the "average consumer" occupies an ambiguous role. By demanding that product warnings adequately address the "average" consumer, the failure-to-warn doctrine seeks to ensure that a manufacturer speak to those people most likely to use its product, about risks that are relevant to them, and in a language that they can understand. Courts in warnings cases, however, have never actually examined the characteristics of an "average consumer" of any defendant's product, even though some particularized understanding of that term might be thought essential to the judicial elaboration of many of the critical requirements of warnings law. Instead of using an "average" geared to each defendant's product, most courts have referred to an imaginary and almost universal construct, the average American adult,\footnote{122} someone who buys every product and for whom an "average" warning, written in English and describing "average" risks, might suffice. No empirical study indicates the proportion of products for which the average American adult is in fact the average consumer. For many products, however, the portrait of the average user must differ markedly from that of the average American, and warnings on those products should ideally take these differences into account.

To protect the informational interests of consumer groups whose

\footnote{121. The real difficulty of this task is highlighted by the debate in scientific circles over whether the format of a warning label matters at all and, if so, which changes in it are more or less efficacious from the consumer’s perspective. In summarizing the scientific literature about consumers’ perceptions of risk and risk information, a recent article concluded that “people’s perceptions of risks are often inaccurate” and colored too deeply by their immediate past experiences, Bettman et al., supra note 85, at 2-5; that consumers “find it difficult to combine multiple items of [risk] information and therefore may be biased in forming perceptions of the overall risk associated with a product that has multiple risks,” \textit{id.} at 6; and that consumers “have great difficulty in making decisions among risky options where [they] could experience a gain or a loss.” \textit{Id.}

122. For the United States as a whole, the statistically average person is a 33-year old white, urban-dwelling female with 12.7 years of formal education. \textsc{U.S. Dep’t of Commerce, Bureau of the Census, Statistical Abstract of the United States: 1990}, at 12, 133 (110th ed. 1990).}
"average" member might not resemble the statistically representative American, judges have created two distinct exceptions to this branch of the adequacy rule. The first, sometimes called the "experienced user" exception, obliges a manufacturer to consider the level of relevant expertise possessed by the typical user of its product and to tailor its warning label to the experience or ability level of that person. Thus, a manufacturer who could reasonably foresee that its product would customarily appeal to very experienced consumers could properly refrain from warning them about risks normally known to experts but not apparent to less experienced users.

Although the theoretical basis for the experienced user exception seems sound, in application the rule poses problems. Since it hinges on notions of relative expertise, the rule is subject to the same kind of definitional uncertainty that plagues other terms in the lexicon of warnings law. While in many cases courts will be able, without difficulty, to separate the expert from the beginner, in many others that task and its logical prerequisite—deciding what constitutes expertise—will be far more troubling. Moreover, some courts further confuse the definitional issue, improperly shifting their inquiry from the manufacturer's reasonable expectations about the user group in general to the particular user/plaintiff's knowledge of the risk that resulted in her injury. This shift in

123. The "experienced user" exception has its genesis in comment k to § 338 of the Restatement (Second) of Torts, which requires the supplier of chattels to warn of inherently dangerous conditions in its products "if, but only if, he has no reason to expect that those for whose use the chattel is supplied will discover its condition and realize the danger involved." Id. See American Mut. Liab. Ins. Co. v. Firestone Tire & Rubber Co., 799 F.2d 993, 994 (5th Cir. 1986).

124. Compare Todalen v. United States Chem. Co., 424 N.W.2d 73, 79-80 (Minn. Ct. App. 1988) (holding that manufacturer must consider user's lack of special knowledge of risks associated with caustic cleaning product in designing and drafting its warning label and that whether such label is adequate is proper question for jury) with DuCote v. Liberty Mut. Ins. Co., 451 So. 2d 1211, 1215 (La. Ct. App.) (holding there was no obligation to inform electrician of risk of electrocution from using ungrounded power saw), cert. denied, 457 So. 2d 100, 103 (1990) (holding no obligation to warn experienced electrician about danger that certain electrical equipment might arc). See also Merklin v. United States, 788 F.2d 172, 178 (3d Cir. 1986) ("[T]he supplier of a dangerous chattel has no duty to warn those who are experienced in the handling of the chattel."); Billiar v. Minnesota Mining & Mfg. Co., 623 F.2d 240, 243 (2d Cir. 1980) ("[N]o one needs notice of that which he already knows."); Toppi v. United States, 332 F. Supp. 513, 517 (E.D. Pa. 1971) (holding no duty to warn exists when user realized dangerousness of chemical). Some courts limit the relevant world of experienced users to "professionals" and "skilled tradespeople," without, however, specifically defining any of those terms. See, e.g., Merklin, 788 F.2d at 178; Billiar, 623 F.2d at 243-44.

125. A recent case from the District of Columbia Court of Appeals typifies this misguided approach. In East Penn Mfg. v. Pineda, 578 A.2d 1113 (D.C. 1990), plaintiff, a truck mechanic with 20 years of experience, was blinded in one eye while attempting to charge a truck battery made by defendant. Id. at 1116. The battery exploded during the charging
emphasis unfairly exposes manufacturers to liability for failing to predict unforeseeable shortcomings in particular plaintiffs.

The pitfalls associated with the experienced user exception, however, pale in comparison to those associated with the other exception to the "average user" rule, which might be called the "linguistic adequacy" exception. This latter exception compels manufacturers to draft their warning labels in a manner comprehensible not just to average users of their products but to smaller groups of non-average users as well. A number of courts interpret this exception to require manufacturers to recognize "the existence of many in the work force who do not read English"126 and to couch their product warnings either in easily understood symbols or in a language that the user can read.127

A requirement that a manufacturer make its warning information intelligible to users who either are not literate at all, or not literate in English, correctly addresses several important social and legal concerns. The number of illiterate and functionally illiterate Americans is very large. According to a 1979 report of the Ford Foundation, twenty-five million Americans cannot read at all and an additional thirty-five million are functionally illiterate.128 Though more recent estimates of the size of this group differ, even the most conservative estimate places the number of functional illiterates at approximately ten percent of the adult popula-

127. See id.; Hubbard-Hall Chem. Co. v. Silverman, 340 F.2d 402, 405 (1st Cir. 1965) (The "jury could reasonably have believed that defendant should have foreseen that its . . . product would be used by, among others, persons . . . of limited education and reading ability," and that its warning, "because of its lack of a skull and bones or other comparable symbols or hieroglyphics," would not be adequate.).
tion. Permitting manufacturers to draft warning labels that ignore such a sizeable portion of the population would work a significant hardship on a particularly disadvantaged segment of society.

Moreover, if product warning labels are properly to serve the function of preventing injury, manufacturers should employ a methodology of information exchange that communicates clearly and effectively with all of the relevant populations at risk. The use of just one kind of warning label, written in English and directed exclusively at literate consumers, not only neglects the needs of other sizeable segments of our population, but also subjects those groups to risks of serious harm that consumers literate in English are helped to avoid. The unfairness of such a regime seems patent.

What to do about that unfairness, however, is a difficult question. Two courts have suggested that in certain circumstances manufacturers should substitute symbols of some kind for the English words that would otherwise comprise their product warnings. For other products, it might be more appropriate to require manufacturers to draft their warnings in Spanish, for example, to meet the risk information needs of this country's largest non-English speaking group. Each of these options raises difficult questions of its own. As to symbols, for instance, when

129. Compare Phillip G. Vargas, In the Shadow of the Mainstream; Without English, My Hispanic Countrymen Are Doomed to Fail in America, WASH. POST, March 31, 1991, at B5 ("[A]bout 56 percent of Hispanic adults are functionally illiterate in English, compared with 44 percent of blacks and 16 percent of whites.") with Zuckman, supra note 128, at 391 (observing that twenty-three million American adults are functionally illiterate and four million are completely unable to read or write).

130. See Hubbard Hall, 340 F.2d at 402 (1st Cir. 1965); Campos, 98 N.J. at 208, 485 A.2d at 305. In neither case, however, did the court indicate which symbols might be appropriate, or to what sources manufacturers might acceptably turn to find appropriate symbols.


132. These needs appear substantial. According to a recent article in The New York Times, Hispanic factory and industrial workers in this country suffer more frequent and more serious job-related injuries than white and black workers in similar jobs. See Peter T. Kilborn, For Hispanic Immigrants, a Higher Job-Injury Risk, N.Y. TIMES, February 18, 1992, at A1.
should they be required? Should they be included on almost all products, since it seems possible that practically any product can be used by practically anyone, literate or not? Or should only that group of products "likely" in some fashion to be used by illiterate or functionally illiterate consumers include such symbols? Further, what proportion of the user group must be illiterate before the manufacturer needs to add a symbolic warning to its written one, or to replace the latter with the former?133 Finally, if we assume that symbols might sometimes be a desirable alternative to written language, which symbols should manufacturers adopt and why?134

Indeed, if the core purposes of failure-to-warn doctrine dictate that product warnings be intelligible to all linguistically significant groups of consumers, how can courts halt the momentum of that dictate short of requiring that manufacturers blanket their products with as many separate warnings as there are "linguistically significant groups"?135 In the absence of such a requirement, large numbers of consumers might not receive risk information that they could fully understand. But the existence of such a requirement could easily spawn comprehensive multi-lin-

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133. In this respect neither Hubbard-Hall nor Campos is particularly helpful. In neither case did the court discuss the numbers or percentages of product users that would need to be illiterate or Spanish-speaking, for example, before a court could properly require a manufacturer to alter or amend its existing warning label. Hubbard-Hall, 340 F.2d at 405; Campos, 98 N.J. at 208, 485 A.2d at 309-11. The reasoning that seems to have fueled the decisions in Hubbard-Hall and Campos is that the particular minority in question, the illiterate or the Spanish-speaking, constitutes an unmeasured but sufficiently large minority of product users to justify a warning label drafted with that minority's specific communication needs in mind. This intuition, logically extended, might require that all products contain either "appropriate" warning symbols or a series of warnings, each in a language intelligible to an unmeasured but "significant minority" of product users.

134. No one has yet developed a set of generally accepted risk or hazard symbols that are comprehensible to most of the populace. Moreover, even if one could devise an acceptable symbolic vocabulary, those symbols would be truly useful only if they were understandable to the illiterate and the functionally illiterate, groups whose comprehension seems particularly difficult to study and test. See W. Kip Viscusi, Reforming Products Liability 145 (1991).

135. The United States Census Bureau does not publish data about the numbers of non-Hispanic minority groups in this country who speak or read in a language other than English. In the past 15 years, however, a number of lawsuits have been brought pursuant to the Bilingual Education Act of 1968, 20 U.S.C. §§ 3221-3262 (1988), alleging that various non-English-speaking groups have been denied the educational assistance promised by the Act. From these suits, it is possible to glean some idea of the numbers of minorities who might benefit from warning labels in their own language. See, e.g., Lau v. Nichols, 414 U.S. 563, 564 (1974) (Chinese speakers); Zambrano v. Oakland Unified Sch. Dist., No. 584503-9 (Alameda Sup. Ct., May 1, 1985) (a class of Cambodian, Filipino, Hispanic, and "other Asian" minorities), cited in Rachel F. Moran, Bilingual Education as a Status Conflict, 73 CAL. L. REV. 321, 335 n.78 (1987).
gual warning labels that might intimidate or confuse consumers, causing them to ignore all of the risk information, including that in their own language.

Although no court has yet extended the logic of the experienced-user and linguistic-adequacy exceptions beyond the obvious parameters of expertise and language, the theoretical influence of these exceptions does not necessarily stop at those borders. If “adequate” product warnings are only those that significant groups of consumers can truly understand, then perhaps manufacturers might eventually have to consider how to gear their warnings to consumers of different race, age, and gender, and makers of children’s products might need to tailor their

136. Susceptibility to alcoholism, for example, may be positively correlated with race. See Stanton Peele, A Moral Vision of Addiction: How People’s Values Determine Whether They Become and Remain Addicts, 17 J. DRUG ISSUES 187, 189-94 (1987). For an opposing view, see John S. Searles, The Role of Genetics in the Pathogenesis of Alcoholism, 97 J. ABNORMAL PSYCHOL. 153, 153-64 (1988). For a bibliography cataloguing the recent studies of alcoholism among blacks, see Thomas D. Watts & Roosevelt Wright, Black Alcoholism, 33 J. ALCOHOL & DRUG EDUC. 76, 78-80 (1988). In the past several years, moreover, a number of manufacturers of alcoholic beverages have developed and marketed certain products specifically for particular racial groups. Power Master, a malt liquor that would have had the highest alcohol content of any malt beverage on the market, was a failed attempt by the G. Heileman Brewing Company to target black consumers. Withdrawn from the market in the summer of 1991 following community protests even before it reached the shelves, Power Master represented the latest in a line of products aimed at discrete groups of consumers, a line that includes Uptown cigarettes (aimed at the black smoker), Cisco fortified wine (the Hispanic buyer), and Dakota cigarettes (“less educated, working women”). Thomas Palmer, A Target-Marketing Ploy Backfires: Malt Liquor Aimed at Blacks Dies Aborning, a Victim of Insensitivity, BOSTON GLOBE, July 14, 1991, (Focus), at 71.

137. It seems intuitively correct, for example, that warnings on products marketed primarily to the elderly should allow at a minimum for the problems of impaired eyesight (which might necessitate the use of larger type in the warning label) and of diminished dexterity (which might require a special emphasis on particular kinds of product risks).

138. In her highly controversial work, the psychologist Carol Gilligan has contended that, starting in early childhood, males and females display strikingly different styles of moral reasoning. See CAROL GILLIGAN, IN A DIFFERENT VOICE 5-23 (1982). While many disagree with Gilligan’s thesis, see, e.g., Catherine Greeno & Eleanor E. Macoby, How Different is the “Different Voice”? 11 SIGNS 310 (1986), many others embrace it as a “feminine vision” of a “virtue-based ideology” that has otherwise been “conspicuously absent from the shaping of [American] moral or political traditions.” Suzanna Sherry, Civic Virtue and the Feminine Voice in Constitutional Adjudication, 72 VA. L. REV. 543, 591 (1986). Gilligan’s perspective might be extended logically, if not empirically, to the notion that women receive and process risk data differently from men.

Some recent cases dealing with claims of sex discrimination in the workplace have analyzed sexual harassment from the particular perspective of women, adopting a methodology of proving discrimination that employs the standard of the “reasonable woman.” Ellison v. Brady, 924 F.2d 872, 879 (9th Cir. 1991) (“[W]e hold that a female plaintiff states a prima facie case of hostile environment sexual harassment when she alleges conduct which a reasonable woman would consider sufficiently severe or pervasive to alter the conditions of employment and create an abusive working environment.”); see also Yates v. Avco Corp., 819 F.2d 630, 637 (6th Cir. 1987) (adopting a reasonable woman standard in sexual harassment case);
warnings to the "reasonable child" of the relevant age group.\textsuperscript{139}

Such an extensive and potentially diverse set of requirements would, as a practical matter, signal an end to the average consumer standard in the area of failure-to-warn. The exceptions would swallow the rule. Even without the judicial adoption of all the exceptions described above, existing departures from the standard have substantially eroded the prevailing rule, perhaps with good reason, and made it much more difficult to apply. In addition to imagining the average consumer, juries must even now attempt to imagine the average expert, the average beginner, the average illiterate, and the average person illiterate in English but literate in another language. They must then decide whether the product warning at issue speaks adequately to the particular listener.

Moreover, the three components of the "adequacy" requirement frequently interact with each other. A change in style or format, for example, could easily disrupt the communicative efficacy of the warning as a whole, necessitating one or more countervailing alterations to other aspects of the warning label.\textsuperscript{140} Consider, for example, a warning adequate in all respects for English-speaking, middle-class women with average experience in using the product. Changing the warning to direct it at an audience, for example, of Spanish-speaking women unfamiliar with the

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\textsuperscript{139} Children's products manufacturers may at least need to draft warnings in a manner that would provide parents with specific instructions about the best way to communicate relevant risk information to the children/users. See, e.g., April A. Caso, Note, Unreasonably Dangerous Products From a Child's Perspective: A Proposal for a Reasonable Child Consumer Expectation Test, 20 Rutger's L.J. 433, 450-59 (1989); Jerry J. Phillips, Products Liability for Personal Injury to Minors, 56 Va. L. Rev. 1223, 1228-31 (1970).

\textsuperscript{140} This phenomenon resembles the problem of polycentricity first articulated by Professor Lon L. Fuller. See Lon L. Fuller, Collective Bargaining and the Arbitrator, 1963 Wis. L. Rev. 3, 4-5. Professor Fuller argued that those matters least amenable to successful adjudication are issues that cannot be analytically isolated; that is, when a litigant's position on one issue would necessarily change in response to the court's resolution of some other issue linked to the first, the issue in question cannot be isolated for purposes of analysis and is subject instead to countless analytical variants. Id. Professor Henderson has argued that the problem of polycentricity infects the judicial resolution of design defect cases. See James A. Henderson, Jr., Judicial Review of Manufacturers' Conscious Design Choices: The Limits of Adjudication, 73 Colum. L. Rev. 1531, 1534-73 (1973).
product, would obviously necessitate a change in the content of the warning—since that type of user will need and want different kinds of risk information—but it might also compel a change in the format of the label, to account for the different ways in which that second group processes risk information. The need to consider this aspect of the adequacy issue multiplies both the complexity involved in drafting an adequate warning and the possibility that any particular warning will in some way be deemed inadequate.

The "adequacy" half of traditional failure-to-warn law is thus equally as problematic as the "risk" half, and perhaps more so. Rather than diminish or disentangle the problems created by the collapse of the obvious and remote danger rules, the adequacy requirements create additional difficulties that amplify the basic dilemmas of warnings doctrine. In elaborating upon the adequacy requirement, courts have announced several distinct rules of "adequacy," each incapable of being usefully defined or coherently described. When applying those rules to specific warning labels, courts scrutinize the wording, location, degree of urgency, type, size, and other attributes of the label's style and content with the microscopic interest and single-minded vigor of medieval monks, criticizing everything but clarifying nothing. Consequently, when the "risk" and "adequacy" halves of warnings law are pieced together, the picture that emerges is one of a doctrine whose two main components defy theoretical coherence and encourage seemingly random results: a risk requirement so open-ended that it is practically all-encompassing, and an adequacy rule so expansive in scope and picayune in application that almost no warning format can consistently satisfy its demands.

IV. THE EFFECT OF THE PARADOXES CREATED BY THE COLLAPSE OF FAILURE-TO-WARN LAW

As a result of the collapse of its limiting rules for risk and of an obsessively baroque approach to its adequacy inquiry, current failure-to-warn doctrine not only confuses the quest for theoretical integrity in warnings cases, but impedes the attainment of the important social goals that animate warnings law. This disarray that defines existing doctrine undermines the institutional interests of courts, manufacturers, and consumers alike.

Because failure-to-warn law lacks internal coherence, courts are unable to articulate rational grounds for deciding and distinguishing particular cases. In the absence of effective limiting rules, the "risk" component of the doctrine has expanded exponentially to include all product-related risk. As a result, those courts that would permit the use
of less inclusive warning labels must not only justify their deviation from the logic of this limitless rule, but must also explain why consumers may lawfully be denied information about risks which are, by definition, legally relevant. At the same time, those courts that would fully enforce this expansive doctrine by insisting on fully comprehensive warnings expose consumers to the prospect of confusion or discouragement over the length or complexity of exhaustive risk information. The rules of adequacy, with their innumerable points of possible insufficiency, do nothing to cabin the notion of risk, but instead force courts to grope for meaningful differences between adequate warnings and perfect ones. For the judiciary, then, the collapse of the limiting rules of obviousness and remoteness, coupled with a minutely detailed approach to warning adequacy, has created a legal doctrine burdened with an insoluble paradox: because almost all risks have come to be defined as legally relevant, an effective warning must mention almost all risks; an all-encompassing warning can dull consumer response to risk information, however, frustrating the adequacy principle of warnings law and undermining the basic doctrinal goal of injury prevention.

Moreover, current law hamstrings manufacturers. Required to provide product warnings, but furnished neither with practical limitations on the kinds of risks that they must mention nor with any useful prescription for a properly drafted warning, manufacturers must attempt an impossible balancing act. They must either describe almost everything that might constitute a hazard, and thus jeopardize the efficacy and intelligibility of their warnings and raise for themselves the prospect of potential liability, or they must knowingly edit from those warnings any mention of possibly obvious or remote risks and thereby flirt with the distinct likelihood that if one of those risks results in serious injury, they will be found responsible. At the same time, they must hope that their choices of language, syntax, format, and location square with the numerous unspoken adequacy criteria of judges and juries. A disembodied risk rule and an incurably recondite inquiry into the particulars of adequacy thus threaten the manufacturer with liability for too much warning and

141. Courts have sometimes permitted plaintiffs to challenge an otherwise adequate product warning by showing that additional, off-label information issued by the defendant diluted the strength of its warning. See, e.g., Stevens v. Parke, Davis & Co., 9 Cal. 3d 51, 65-69, 507 P.2d 653, 661-64, 107 Cal. Rptr. 45, 53-56 (1973) (holding that the potential dilution of product warning by overpromotion of drug by salespeople is question for jury); Incollingo v. Ewing, 444 Pa. 263, 300, 282 A.2d 206, 221-22 (1971) (same decision in case involving the promotion of chloromycetin to the medical profession). The logical bridge extending liability from off-label information that dulls a warning's acuity to on-label information with the same effect does not seem very long.
liability for too little warning, without providing any real clue as to what constitutes too much or too little.

Finally, although class-based logic might suggest that what harms manufacturers must help consumers, it seems much more likely that product users suffer as well from the confusion that dominates warnings law. By neglecting to establish workable standards for manufacturers, courts subject product users to the perplexing and unpleasant prospect of a regime of warnings that are sometimes incomplete and sometimes too complete, but that need not conform to any set of considered criteria. By exposing manufacturers to seemingly random liability for breaches of the adequacy requirement, courts discourage them from developing processes that might rationalize and systematize the drafting of product warnings and that might better serve consumer health. By adhering to a content-based method of decision focused exclusively on a particular circumstantial mix of risk, harm, and warning, courts create remedies for individual consumers after the injury, instead of promoting prevention beforehand for large groups of consumers. By failing to forge a doctrinal alternative to their inevitably unsatisfying inquiry into the substance of particular warnings, courts also abandon the safety interests of consumers generally, protect the rights only of the relatively few that bring suit, and increase the exposure of most consumers to product-related harm, the very consequence that the law of failure-to-warn attempts to avoid.

V. THE CAUSATION COMPONENT OF FAILURE-TO-WARN

Traditionally, in order for a plaintiff to prevail on his claim in tort,
he must prove causation. Generally, this requirement has several parts. First, the behavior on which liability is predicated has to be a "but-for" cause (or a cause-in-fact) of the injury. Second, that behavior must be related proximately to the injury. The causation requirement thus obliges plaintiffs to demonstrate the factual and legal etiological connection between their harm and the defendant's act or omission.

As with the other essential elements of a negligence action for which the plaintiff normally bears the burden of proof, courts occasionally shift the causation burden or otherwise adjust it in the general interests of fairness. It might seem logical that in order to contain the damage done by the collapse of the risk and adequacy rules, courts should alter the causation burden in warnings cases to make it more demanding for plaintiffs and should then use that higher standard to sift the arguably "weak" cases from the larger pile of claims amassed, in part,

143. See generally H.L.A. Hart & Tony Honore, Causation in the Law (2d ed. 1985) (examining the development of the causation requirement); Restatement (Second) of Torts § 430 (1964) (outlining general principles of causation).
144. See generally Restatement (Second) of Torts § 432 (1964) (noting that, in most cases, the behavior must be a "substantial factor" in bringing about the harm).
147. The essential elements of negligence are duty, breach, and harm. See Keeton et al., supra note 91, § 30, at 164-65.
148. Id. at 239.
149. This burden-shifting sometimes occurs with the elements of duty and breach, as witnessed by the development and expansion of the doctrine of res ipsa loquitur, see, e.g., Ybarra v. Spangard, 25 Cal. 2d 486, 490, 154 P.2d 687, 689 (1944), and also occurs, quite dramatically in recent years, with respect to causation. See, e.g., Sindell v. Abbott Lab., 26 Cal. 3d 588, 611-13, 607 P.2d 924, 937, 163 Cal. Rptr. 132, 145 (1980) (burden of proving causation shifted under theory of "market share liability"); Summers v. Tice, 33 Cal. 2d 80, 88, 199 P.2d 1, 5 (1948) (burden of proving causation shifted to defendants under theory of "alternative liability"); see also Brown v. Superior Court (Abbott Lab.), 44 Cal. 3d 1049, 1069-71, 751 P.2d 470, 483-84, 245 Cal. Rptr. 412, 424-26 (1988) (noting the "market share" theory in support of a shift of the burden of proof to defendants); Hymowitz v. Eli Lilly & Co., 73 N.Y.2d 487, 505-12, 539 N.E.2d 1069, 1074-78, 541 N.Y.S.2d 941, 945-50 (discussing the validity of several theories of recovery to provide plaintiffs with a cause of action and support a granting of relief to plaintiffs), cert. denied, 493 U.S. 944 (1989).
from the failure of the risk and adequacy sieves. In fact, however, the courts have done no such thing.

Instead of cushioning the impact of the risk and adequacy problems by adding to a plaintiff's burden of proof on causation, courts have erred in the opposite direction. In so doing, the courts have eased that burden and amplified the effect of those already formidable problems. Several commentators have perceptively described some aspects of the causation quandary in warnings law, arguing that a plaintiff's prima facie proof of causation is too easy to establish, too difficult to rebut, and practically impossible to prove as a matter of science. Those commentators contend that these elements turn the causation question into "a mirage," contribute to a standard "without content," and result in an analysis that is "completely ad hoc." They claim, however, that the complications inherent in this methodology could be readily untangled, if courts would simply abandon the pro-plaintiff presumption arguably derived from comment j to section 402A of the Restatement (Second) of Torts and replace it with "a more fact-intensive approach."

For the reasons described below, this claim fails to strike effectively at the heart of the causation problem in failure-to-warn law. Whether proved objectively or subjectively, factually or intuitively, causation in warnings cases is peculiarly and innately a simple matter for plaintiffs. No amount of judicial tinkering can make it otherwise. Altering the terms of the causation requirement cannot redress the doctrinal imbalance created by the indeterminacy of the concepts of risk and adequacy.

150. Doctrinal Collapse, supra note 13, at 305-10.
151. Id. at 307.
152. Id. at 308-09.
153. Id. at 310.
154. Comment j provides: "Where warning is given, the seller may reasonably assume that it will be read and heeded; and a product bearing such a warning, which is safe for use if it is followed, is not in defective condition, nor is it unreasonably dangerous." RESTATEMENT (SECOND) OF TORTS § 402A cmt. j (1965). The causation presumption arguably arising from that comment holds in effect that if courts must presume that users would read and heed an adequate warning actually provided them, then courts must also presume, by a process of converse reasoning, that consumers would have read and heeded an adequate warning, in those cases where the manufacturer failed to give them one. See, e.g., Benoit v. Ryan Chevrolet, 428 So. 2d 489, 493 n.8 (La. Ct. App. 1982); Cunningham v. Charles Pfizer & Co., Inc., 532 P.2d 1377, 1382 (Okla. 1974); Menard v. Newhall, 135 Vt. 53, 54-55, 373 A.2d 505, 506-07 (1977); see also 3 AM. L. PRODS. LIAB. § 32:74, at 117-18 (3d ed. 1987) (discussing presumptions and burden of proof in product liability cases; citing cases in support of the issues described therein).
155. Doctrinal Collapse, supra note 13, at 326 n.250 (citing as an example of a better approach that taken in Raney v. Owens-Illinois, Inc., 897 F.2d 94, 95-96 (2d Cir. 1990) (causation should not be presumed but "may sometimes be inferred from the facts and circumstances").)
Neither shifting nor strengthening the burden of proof for that requirement can bring coherence to a basically amorphous body of law.

As with proof of causation in negligence actions generally, proving causation in failure-to-warn cases usually requires that a plaintiff establish several critical facts. In all cases, the plaintiff must first show that the manufacturer failed either to place a warning label on its product or to make its existing warning label legally adequate. This requirement is not part of the causation inquiry, but goes instead to the question of whether the defendant has breached a duty that it owes to the plaintiff. Unless the plaintiff can satisfactorily prove duty and breach, the causation question is moot. The plaintiff must then show that he would have read, understood, and heeded an adequate warning, thus avoiding the injury in question. If the plaintiff establishes all of these facts, he will have demonstrated the requisite link between his own harm and the defendant's failure to provide an adequate warning.

In other areas of product liability law, those involving alleged defects of manufacturing and of design, proving causation is often a difficult matter for plaintiffs. The possibility of product misuse or mishandling, either by the plaintiff or others, complicates the showing in the former type of case; in the latter, the need for the plaintiff to suggest a

156. See, e.g., E.R. Squibb & Sons, Inc. v. Cox, 477 So. 2d 963, 969-70 (Ala. 1985); Mampe v. Ayerst Lab., 548 A.2d 798, 801-02 (D.C. 1988); Jacobs v. Technical Chem. Co., 480 S.W.2d 602, 604 (Tex. 1972). The Model Uniform Products Liability Act provides that a plaintiff must prove "by a preponderance of the evidence that if adequate warnings had been provided . . . a reasonably prudent product user would have either declined to use the product or would have used the product in a manner so as to have avoided the harm." MODEL UNIFORM PROD. LIABILITY ACT § 104(c)(3) (1979).


158. Professor Epstein, for example, has observed that questions of proof in this area "can be formidable, especially for long-lived products or those that receive intensive and protracted use." RICHARD A. EPSTEIN, CASES AND MATERIALS ON TORTS 665 (5th ed. 1990); see, e.g., State Farm Fire & Cas. Co. v. Chrysler Corp., 37 Ohio St. 3d 1, 7-9, 523 N.E.2d 489, 494-96 (1988) (rejecting plaintiff's attempt to use the doctrine of res ipsa loquitur to prove defect in car's electric wiring). See generally Paul D. Rheingold, Proof of Defect in Product Liability Cases, 38 Tenn. L. Rev. 325, 325-43 (1971) (describing and analyzing various methods of proving the existence of a defect in products litigation).
viable alternative to defendant's existing product design in order to pre-
vail under standard risk-utility analysis usually requires that he present
expert testimony that a specific alternative design, safer than defendant's
and commercially feasible, could have prevented his injuries.\footnote{159}

In the failure-to-warn area, the causation difficulties found in cases
of manufacturing or design defect do not exist. For warnings claims,
almost all courts have adopted one of two approaches to causation, either
of which makes it relatively easy for plaintiffs to satisfy their burden of
proof. Some courts employ the pro-plaintiff presumption derived from
\citecomment{160} a measure that frees plaintiffs from the obligation to prove
either their general inclination to read and obey product warnings or the
fact that they have actually done so in the particular case. All of that
critical evidence is presumed. Although the presumption is rebuttable, it
would nevertheless seem that defendants seeking to rebut it (by showing,
for example, that plaintiff was the kind of reckless person who habitually
ignored his own safety in general, and warning labels in particular)
would do so at some substantial peril to any positive regard that the jury
might have for them. Rare indeed are cases involving the admitted fail-
ure by plaintiff to read an allegedly inadequate warning.\footnote{161}
The adoption
of this pro-plaintiff presumption thus seems virtually to guarantee that
plaintiffs in warnings cases will be able to prove causation with little
difficulty.

Not all courts have adopted this pro-plaintiff presumption as to cau-
sation. Those declining to do so have nevertheless found an alternative
mechanism that alleviates a plaintiff's potential difficulties of proof. In
these jurisdictions, courts employ a subjective standard for establishing
causation, allowing a plaintiff to testify—after the fact of his injury, of
course—as to whether he would have read and heeded an adequate warn-
ing had the defendant placed one on its product.\footnote{162} This kind of inquiry
does not produce much in the way of surprise. Plaintiffs invariably say
that they would have read the missing or inadequate warning and that

\footnote{159. \textit{See}, \textit{e.g.}, Hull v. Eaton Corp., 825 F.2d 448, 453-55 (D.C. Cir. 1987) (requiring plain-
tiff to prove the relative risks and costs of alternative designs in order to prevail on design
defect claim against manufacturer of forklift); Brady v. Melody Homes Mfr., 121 Ariz. 253,
259, 589 P.2d 896, 900 (1979) (same with regard to design defect claim against maker of
mobile homes); Byrns v. Riddell, Inc., 113 Ariz. 264, 268, 550 P.2d 1065, 1068 (1976) (same as
to maker of football helmets).

160. \textit{RESTATEMENT (SECOND) OF TORTS} § 402A cmt. j (1965); \textit{see supra} note 154 and
accompanying text.

161. Such cases are rare, but not unknown. \textit{See}, \textit{e.g.}, Mampe v. Ayerst Lab., 548 A.2d 798,

162. \textit{See}, \textit{e.g.}, Laaperi v. Sears, Roebuck & Co., 787 F.2d 726, 730 (1st Cir. 1986) (finding
plaintiff's own testimony that he would have heeded a warning if given one sufficient to estab-
lish proximate cause).
they would have heeded it as well. As with the pro-plaintiff presumption discussed above, defendants have the opportunity on cross-examination to attack plaintiff's testimony on this score, but the strategical risks of attempting such an attack are, once again, substantial. In these jurisdictions, as in those adopting the pro-plaintiff presumption, most plaintiffs have practically proven causation before their trial even begins.

In theory, there exists a third approach to the causation inquiry: the objective approach. This approach would neither allow for a pro-plaintiff presumption nor permit the plaintiff to testify about her hypothetical reactions to an adequate warning. Rather, it would ask whether a reasonable person in plaintiff's circumstances immediately before the accident in question would have read and heeded an adequate product warning. Such an approach would not be new to tort law. In the area of informed consent to medical treatment, for example, a significant number of courts have decided that the better method of resolving the causation question is to ask "what a prudent person in the patient's position would have decided if suitably informed of all perils bearing significance."163

An objective method of establishing causation in warnings cases would arguably have all of the advantages usually attributed to objectivity. Instead of relying on the post-injury testimony of an inevitably biased, seriously injured plaintiff, and instead of presuming that every plaintiff will always read and obey every warning, the objective approach would concentrate on the course of conduct that would have been taken before the injury by a hypothetical reasonable person. If that person would have read and obeyed an adequate warning, then a jury could fairly conclude that defendant's negligence in failing to provide such a

163. Canterbury v. Spence, 464 F.2d 772, 791 (D.C. Cir.), cert. denied, 409 U.S. 1064 (1972), was the first opinion to adopt the objective approach to causation in informed consent cases. The court there explicitly rejected the subjective approach, declaring that it placed the factfinder in the position of "deciding whether a speculative answer to a hypothetical question is to be credited," and called for a determination based solely on the "testimony of a patient-witness shadowed by the occurrence of the undisclosed risk." Id. The court continued, "Better it is, we believe, to resolve the causality issue on an objective basis: in terms of what a prudent person in the patient's position would have decided if suitably informed of all perils bearing significance." Id.

California was one of the first states to adopt the objective standard announced in Canterbury. See Cobbs v. Grant, 8 Cal. 3d 229, 245, 502 P.2d 1, 11, 104 Cal. Rptr. 505, 515 (1972). The Cobbs court held that the objective standard, though not completely consonant with the principle of patient autonomy, is nevertheless preferable because it does not place the physician "in jeopardy of the patient's bitterness and disillusionment" that might arise with "the vision of 20/20 hindsight." Id. New Jersey, in Largey v. Rothman, 110 N.J. 204, 540 A.2d 504, 510 (1988), was one of the most recent jurisdictions to adopt the objective standard. Id. at 214-15, 540 A.2d at 509-10. Oregon, among others, has rejected the objective test. See Arena v. Gingrich, 305 Or. 1, 5-6, 748 P.2d 547, 549-50 (1988).
warning caused plaintiff's injury. If not, then the plaintiff could not pre-
vail on the causation issue and would therefore lose her case.

On its surface the objective approach may seem different from, and
fairer than, both its subjective alternative and the more explicitly pro-
plaintiff presumption previously described. By eliminating a fixed pre-
sumption, on the one hand, and the plaintiff's own necessarily predict-
able testimony on the other, and replacing them with an inquiry into the
hypothetical ex ante actions of a reasonable consumer, the objective ap-
proach might appear to offer factfinders a neutral way of resolving the
causation issue. For all practical purposes, however, its adoption would
not change or unravel the causation dilemma in any meaningful way.

The hypothetical reasonable person will always read and obey an
adequate warning label. The costs of doing so are minimal—a few min-
utes, at most, spent in the process of reading—and the benefits are enor-
mous—the avoidance of serious personal injury or property damage.
Reading and obeying warning labels, therefore, must define the activities
of the reasonable person, while failing to read or obey them must be a
sure sign of irrationality."¹⁶⁴ This truism would always end the causation
inquiry, perhaps more decisively in plaintiff's favor than either of the two
openly pro-plaintiff approaches. Consequently, if the current methods of
dealing with the causation issue seem problematic because they require
too little of the plaintiff, the adoption of an objective approach to causa-
tion would not seem to be the answer because it would require even less.

Since each of the possible approaches to causation has significant
weaknesses and no other satisfactory approach exists, failure-to-warn law
is left with a Hobson's choice of causation methodologies, doomed to
select one that does not function well. Of course, the need to choose
among poorly functioning legal principles is not unique to this area of
law, but again, it is made much more acute here, and much more harm-
ful, by the collapse of the "risk" and "adequacy" components of the doc-
trine. Because the emptiness of those components effectively removes
from warnings law the theoretical limitations on plaintiff's proof of duty
and breach, it might seem essential, in order to preserve the last shreds of
doctrinal integrity, that courts apply causation principles to limit the ease

¹⁶⁴ In this respect, the causation issue in failure-to-warn cases differs critically from that
in informed consent cases. In the former type of case, it is difficult to imagine a situation in
which the application of the objective standard for causation would lead to the conclusion that
it was reasonable not to have read the warning label. In the latter type, however, the plaintiff's
cost-benefit calculus is very different and would sometimes lead the hypothetically reasonable
patient to proceed with the operation that ultimately turns out badly, even after having been
informed of all material risks.
with which plaintiffs can make out a prima facie claim.\textsuperscript{165} By achieving precisely the opposite result, however, the various approaches to proof of causation amplify the impact of those other shortcomings and practically ensure plaintiff’s ultimate success at trial. Given the nature of this particular causation inquiry, and because there is no plausible pro-defendant approach to causation in warnings law, no other outcome is possible. As a result, failure-to-warn law, a doctrine meant to be clothed in negligence, has assumed instead the garb of strict liability. The inevitable consequences of causation methodology make this change of costume complete.\textsuperscript{166}

VI. CURRENT CRITICISMS OF FAILURE-TO-WARN LAW

Recently, several prominent academicians have criticized failure-to-warn law, pointing out many of the same problems discussed above.\textsuperscript{167}

\textsuperscript{165} Causation principles are not meant to serve this purpose, nor are they able, by themselves, to compensate fully for the other doctrinal distortions in failure-to-warn law. If they are to be conscripted, however, to help in a struggle that was not of their making, rules of causation should be used to rationalize existing doctrine, not to destabilize it further.

\textsuperscript{166} The two major dilemmas of usefully defining risk and adequacy, and of employing a more restrictive concept of causation, by no means exhaust the list of significant doctrinal problems that bedevil the law of failure-to-warn. A full discussion of all of those problems is beyond the scope of this article; nevertheless, some deserve at least a passing mention.

Courts have long recognized two distinct kinds of duty to warn. The first kind, which constitutes the main concern of this Article and is by far the more prolific source of litigation, concerns the manufacturer’s obligation at the point of sale and asks how much and what sort of risk information need be on the product when the consumer buys it. The second kind, alternately called the “post-sale” or “continuing” duty to warn, requires a manufacturer, who discovers after its product has been marketed that the use of its product entails risks not mentioned in the existing warning label, to make “reasonable efforts” to issue post-sale warnings to product users. See, e.g., Comstock v. General Motors Corp., 358 Mich. 163, 176, 99 N.W.2d 627, 634 (1959) (having discovered defects in its cars’ braking system after the cars had been on the market, GM was obliged “to take all reasonable means to convey effective warning” to the car buyers); see also Braniff Airways, Inc. v. Curtiss-Wright Airways Corp., 411 F.2d 451, 453 (2d Cir.) (holding that a manufacturer aware of “dangerous” defects in its product has “continuing duty” to improve it and to give users “adequate” warning), cert. denied, 396 U.S. 959 (1969). The practical difficulties associated with a continuing duty to warn, and the efficacy of court-ordered product recall as an alternative to the arguable inefficiencies inherent in a system of post-sale warning, have provided significant food for academic thought. See, e.g., Robert B. Patterson, \textit{Products Liability: The Manufacturer’s Continuing Duty to Improve His Product or Warn of Defects After Sale}, 62 ILL. BAR J. 92, 93-98 (1973); Victor Schwartz, \textit{The Post-Sale Duty to Warn: Two Unfortunate Forks in the Road to a Reasonable Doctrine}, 58 N.Y.U. L. REV. 892, 895-97 (1983); Bernard W. Bell, Note, \textit{The Manufacturer’s Duty to Notify of Subsequent Safety Improvements}, 33 STAN. L. REV. 1087, 1093-99 (1981); Dale Car- rington, Note, Bell Helicopter v. Bradshaw: The Existence of a Better System and a Duty to Warn as a Basis for Product Liability Recovery, 22 S. TEX. L.J. 168, 170-75 (1982); Stanton A. Shafer, Comment, \textit{Products Liability: Post-Sale Warnings}, 1978 ARIZ. ST. L.J. 49, 55, 64-68. These problems still exist in large measure and add to the complexity and confusion of current failure-to-warn doctrine.

\textsuperscript{167} See generally AMERICAN LAW INSTITUTE, supra note 13 (summarizing warning
While some of those criticisms are insightful, their approaches to rehabilitating the doctrine share the same fundamental error. Each suffers from the naive view that the existing doctrine can be fixed with a little tinkering here and a few adjustments there. Each wrongly encourages courts to keep their gaze fixed on the content of the terms "risk" and "adequacy"; each wrongly suggests that with a few simple corrections to judicial eyesight, the fuzzy contours of those terms can be made clear and comprehensible.

A. The Henderson-Twerski Critique

Professors Henderson and Twerski have engaged in a lengthy examination of the obvious danger rule, first praising it for possessing enormous potential for limiting and clarifying warnings law, but then expressing amazement that so many courts seem unable to do in practice what in theory appears simple to the authors: recognize "obviousness" when one sees it. For reasons inexplicable to Henderson and Twerski, the case digests "abound" with doctrinal anomalies, seemingly aberrational opinions where judges have unaccountably failed to discern the obviousness of a particular risk and wrongly permitted plaintiffs to proceed to trial.

The case reports teem with those so-called anomalies because courts cannot reach universal agreement about what constitutes an "obvious" risk. Professors Henderson and Twerski appear to recognize this fact, but attribute it to an unreasoned willingness on the part of many courts to allow "too many cases" to "make their way to juries." To remedy this judicial failing, they urge simply that "the standard of obviousness must rise"; but they do not, because they cannot, propose any specific suggestion for levitating that standard. Consequently, their solution to the predicament produced by the collapse of the obvious danger rule is simply an exhortation that courts try harder to recognize obviousness problems and proposing guidelines for manufacturers in creating defenses to liability); Part I (outlining and discussing the problems attendant to failure-to-warn law, including unknowable risks and strict liability, causation presumption when no adequate warning is given, and lack of restraints on jury discretion).

169. Id. at 280 ("Perhaps more than any other aspect of warnings doctrine, this traditional rule should help courts cull unworthy failure-to-warn claims from the worthy.").
170. Id. at 284-85.
171. Id. at 317.
172. "Perhaps what has happened in failure-to-warn cases is that courts, uncharacteristically, have gone too far in imposing an open-ended duty to rescue." Id. at 311.
173. Id. at 316.
174. Id. at 317.
Henderson and Twerski have an equally nebulous response to the causation dilemma. Following an excellent discussion of the problems that bedevil the causation inquiry in warnings cases, they suggest that courts should resolve those problems by abandoning the presumptions and rules favoring plaintiffs and replacing them with "a more fact-intensive approach." Regrettably but perhaps inevitably, Henderson and Twerski fail to identify even one type of fact whose proof might improve the current method of treating causation, and they neglect to articulate any way in which their approach would mend the flaws in the status quo. If courts discard the current pro-plaintiff presumptions and require plaintiffs to testify about their likely responses to a hypothetically adequate warning, the testimony on causation will still be predictable, and the larger causation inquiry presumably expanded to consider those unnamed facts that Henderson and Twerski believe are now being overlooked, will still present the practical difficulties described earlier in this Article and recognized clearly by Henderson and Twerski themselves.

Finally, Henderson and Twerski recount some of the problems intrinsic to the various "adequacy" rules discussed earlier in this article. They mention, for example, the ease with which courts apply risk-utility analysis to justify and require additional warnings sought by plaintiffs. They point out the difficulties in harnessing modern communications theory to the service of failure-to-warn law. They further note the relative facility with which courts routinely decide that questions of warning label format can properly be sent to the jury.

For these problems of adequacy, and for the other doctrinal complications as well, Henderson and Twerski recommend a three-pronged solution. They suggest that courts "simply should refuse to hold defendants liable for failing to include one more tiny piece of informa-

175. At the other end of the risk spectrum, Henderson and Twerski acknowledge that the remoteness rule has even fewer teeth than its obviousness counterpart. Id. at 294 n.122 ("Many more decisions deny liability for failure to warn as a matter of law on the ground that the risk is obvious than do so on the ground that the risk is remote."). However, because they think the obviousness rule can be rehabilitated by a collective act of judicial will, they do not recognize that the inevitable failure of both rules destroys any possibility that failure-to-warn doctrine might function effectively.

176. Id. at 303-10.
177. Id. at 326.
178. Id. at 306.
179. Id. at 293-95.
180. Id. at 297-99.
181. Id. at 309.
tion” in their warnings. They argue that courts must defer “more readily to other decision-makers who do possess the institutional capability to assess warnings as a whole.” They also propose that courts “demand greater procedural rigor in the litigation process, directing verdicts more readily in unworthy cases.”

Each of these proposals is ultimately unsatisfying. Consider the final one first. Although Henderson and Twerski advocate the injection of “greater procedural rigor in[to] the litigation process,” they refrain completely from describing this “rigor,” other than to refer to it obliquely as “starch” and “tension.” At the same time, they supply no clues that could help solve the ultimate riddle of failure-to-warn: how to define an adequate warning and distinguish it from an inadequate one. This proposal, then, amounts to no more than academic cheerleading, the expression of an amorphous but well-meaning belief that courts can do better in this area if they really, really try.

The second proposal, though somewhat more specific, also misses the mark. In order to allow for systematic and expert consideration of warning labels as a whole, Henderson and Twerski argue that courts “could at least pay more serious attention” to the conclusions about warning labels reached by federal agencies and commissions. Again, since they do not indicate how much more attention courts should pay to these agencies, this proposal also lacks the kind of specificity that might make it meaningful.

182. Id. at 314.
183. Id. at 313.
184. Id.
185. Id. at 322.
186. Id. at 320. Henderson and Twerski name the Food and Drug Administration and the Consumer Product Safety Commission as two of the “product safety agencies” to which courts should defer. Id. Their confidence in the F.D.A. as a lodestar of regulatory efficiency seems sadly misplaced, particularly in light of the recent and heavy criticism leveled at that agency for its failure to describe and regulate the risks associated with silicone-filled breast implants. See From No Scrutiny to Federal Regulation, N.Y. TIMES, Nov. 5, 1991, at A18. Their trust in the CPSC appears equally suspect. See, e.g., Jean A. Langlois et al., The Impact of Specific Toy Warning Labels, 265 JAMA 2848-50 (June 5, 1991).
187. A number of states provide by statute that a manufacturer whose product warning complies with state or federal laws or regulations shall benefit from a rebuttable presumption that its warning is not defective. See, e.g., COLO. REV. STAT. § 13-21-403(1)(b) (1977); KAN. STAT. ANN. § 60-3304 (1983); N.J. STAT. ANN. § 2A:58C-4 (West 1987); N.D. CENT. CODE § 28-01.1 to -05(3) (1991); TENN. CODE ANN. § 29-28-104 (1980). The Tennessee statute is typical. It states that:

Compliance by a manufacturer or seller with any federal or state statute or administrative regulation existing at the time a product was manufactured and prescribing standards for . . . warning or instructions for use of a product, shall raise a rebuttable presumption that the product is not in an unreasonably dangerous condition in regard to matters covered by these standards.
Even if Henderson and Twerski could satisfactorily quantify the desirable degree of judicial attention to agency rules, courts might with good reason question the wisdom and efficacy of protecting consumer interests by deferring to those rules. Over the past three decades, commentators from all parts of the political and academic spectrum have attacked the premise that the regulatory process can fairly and effectively protect or enhance consumer welfare. At the same time, the specific federal regulations that govern warning labels for cigarettes, alcoholic
beverages,\(^\text{190}\) and toys containing small parts\(^\text{191}\) have all drawn serious criticism from both legal and scientific commentators,\(^\text{192}\) not only because they arguably fail to provide consumers with useful risk informa-

U.S.C. §§ 1331-1340). The 1984 amendments created a scheme requiring the following four separate warning labels to appear, one at a time, in alternating sequence on cigarette packages:

SURGEON GENERAL'S WARNING: Smoking Causes Lung Cancer, Heart Disease, Emphysema, and May Complicate Pregnancy.; SURGEON GENERAL'S WARNING: Quitting Smoking Now Greatly Reduces Serious Risks to Your Health.; SURGEON GENERAL'S WARNING: Smoking by Pregnant Women May Result in Fetal Injury, Premature Birth, And Low Birth Weight.; SURGEON GENERAL'S WARNING: Cigarette Smoke Contains Carbon Monoxide.


190. The Alcohol Beverage Labeling Act of 1988 (ABLA) prohibits the manufacture, importation, or bottling for sale or distribution in the United States, of any alcoholic beverage, unless the beverage container carries the following statement: "GOVERNMENT WARNING: (1) According to the Surgeon General, women should not drink alcoholic beverages during pregnancy because of the risk of birth defects. (2) Consumption of alcoholic beverages impairs your ability to drive a car or operate machinery, and may cause health problems." 27 U.S.C. § 215 (1988).

191. In 1980 the Consumer Product Safety Commission (CPSC) promulgated its "small parts" standard. 16 C.F.R. §§ 1500.18(a)(9), 1501 (1992). This standard applies to all toys sold in interstate commerce, and effectively prohibits the manufacture and sale of toys to children below the age of three, if the toys themselves or any of their detachable components meet the statutory definition of "small parts," a term defined by reference to specific measurements. Toys containing small parts can be lawfully sold provided that they are not marketed to children under the age of three. In order to comply with this standard, toy manufacturers generally place age labels on the packaging of their products, though they are not required to do so by the CPSC. The CPSC does, however, provide toy manufacturers with guidelines for age labeling that direct the manufacturers to consider developmental appropriateness and safety in recommending a particular toy for a particular age group of children. See Langlois et al., supra note 186, at 2848-50.


For legal scholarship that questions the informational and scientific efficacy of the warning labels required by the Alcohol Beverage Labeling Act of 1988, as well as the harmful prospects created by that Act's probable preemptive effect, see Michael S. Jacobs, The Alcohol Beverage Labeling Act of 1988: A Critical Analysis, 40 SYRACUSE L. REV. 1223, 1231-36 (1989). Although the ABLA's warning scheme has been in effect for only two years, some members of Congress already deem it inadequate and have recently proposed legislation that would require alcohol-related advertising to alternate one of five separate warning statements. See Philip J. Hitts, Alcohol Ads Criticized as Appealing to Children, N.Y. TIMES, November 5, 1991, at A16.

For an empirical study that casts significant doubt on the utility and intelligibility to toy
tion, but also because preemption clauses in some federal warning legislation\textsuperscript{193} probably serve to insulate the statutory warnings from state court attack, freezing in place warning formats that may be untested and warning language that may be ill-considered, outdated, or ambiguous.\textsuperscript{194} For these reasons, proposals to fix warnings law by entrusting its care to the unwieldy, ineffective, and possibly preemptive processes of federal regulatory agencies not only cut directly against the grain of modern academic wisdom but threaten as well to cause more harm than good.\textsuperscript{195}

\textsuperscript{193} The preemption section of the Federal Cigarette Labeling and Advertising Act, 15 U.S.C. §§ 1331-1341 (1988), whose warning requirements are set forth supra note 189, reads as follows:

Section 1334. Preemption

(a) Additional Statements. No statement relating to smoking and health, other than the statement required by section 1333 of this title [the warning label], shall be required on any cigarette package.

(b) State Regulations. No requirement or prohibition based on smoking and health shall be imposed under State law with respect to the advertising or promotion of any cigarettes the packages of which are labeled in conformity with the provisions of this chapter.

\textit{Id.} § 1334.

Section 216 of the Alcohol Beverage Labeling Act of 1988, whose warning requirements are set forth supra at note 190, provides:

No statement relating to alcoholic beverages and health, other than the statement required by section 215 of this title [the warning label], shall be required under State law to be placed on any container of an alcoholic beverage or on any box, carton, or other package, irrespective of the material from which made, that contains such a container.


\textsuperscript{194} See Jacobs, supra note 192, at 1236-1249. Because of the likely preemptive effect of the ABLA on state court actions alleging the inadequacy of warning labels, the dilemmas posed by cases such as Joseph E. Seagram & Sons, Inc. v. McGuire, 814 S.W.2d 385 (1991), discussed supra at notes 51-61 and accompanying text, and others alleging failure to warn about the risks of consuming alcoholic beverages, have probably been mooted, at least as of November 18, 1989, the effective date of the warning label requirements contained in the federal legislation. 27 U.S.C. § 215(a) (1988).

\textsuperscript{195} In one of his earlier articles, Professor Twerski advocated an approach to agency-made product standards that is much more cautious than the one that he now proposes. In discussing whether courts should defer in products liability cases to standards promulgated by the then newly-established Consumer Product Safety Commission (CPSC), Professor Twerski and his co-authors criticized the lack in the CPSC statutory framework of a formalized method for assuring consumer input to the regulatory process and argued that:

Given the context of this statutory framework, it is not at all clear that independent evaluation by the courts within the context of the private lawsuit is undesirable. When one adds the tendency of administrative agencies to develop an industry orientation with the passage of time, the argument for an independent forum to examine standards is a potent one.

Use and Abuse of Warnings, supra note 11, at 537.
The traditional judicial approach to manufacturer compliance with agency-made warnings, that it constitutes some evidence of care but not conclusive evidence, should be left alone.

Henderson and Twerski's first proposal is no better than their other two and, because it ignores what is one of the major problem of warnings law, is probably worse. By urging courts to refuse to hold manufacturers liable for failing to add "insignificant increments" to their warning labels, Henderson and Twerski encourage courts to act in precisely the way that courts probably believe they are acting now. The quandary of warnings law does not stem from a judicial proclivity to demand additional insignificant bits of information. Rather, the law has become mysterious because, by defining almost all risk information as significant, courts have left themselves with no reasoned basis for permitting manufacturers to exclude any risk information from warning labels. By encouraging continued judicial emphasis on the content of warning labels, Henderson and Twerski's proposal would further obscure this mystery, not illuminate it.

B. The Reporters' Study to the American Law Institute

The other major academic effort recently to analyze warnings law suffers from many of the same shortcomings found in the Henderson-Twerski work. The Reporters' Study to the American Law Institute, enti-


197. The Henderson-Twerski "deference to experts" proposal actually has three parts. The second part urges courts to accord "some" weight to industry standards regarding product warnings and, particularly, to give "substantial weight" to evidence that an entire industry "or a substantial portion thereof" has adopted specific customs pertaining to warning labels. Doctrinal Collapse, supra note 13, at 322. This proposal suffers from the same problems of ambiguity (how much is "some"?) and of institutional competence (why defer to an industry custom that might not be demonstrably intelligent?) that characterize the first part of their proposal. Cf. The T.J. Hooper v. Northern Barge Corp., 60 F.2d 737, 740 (2d Cir.) ("[A] whole calling may have unduly lagged in the adoption of new and available devices... Courts must in the end say what is required; there are precautions so imperative that even their universal disregard will not excuse their omission.") (Hand, J., delivering the opinion of the court), cert. denied, 287 U.S. 662 (1932).

The third part is somewhat schizophrenic. Acknowledging that the role of expert witnesses in products liability litigation has recently come under heavy attack, see, e.g., Chaulk v. Volkswagen of Am., Inc., 808 F.2d 639, 643-45 (7th Cir. 1986) (Posner, J., dissenting), and realizing explicitly that their own analysis suggests "that expert testimony can be extremely problematic in the failure-to-warn context," Henderson and Twerski nevertheless contend that experts can serve the useful purpose of educating the courts about the "truly difficult policy choices" in failure-to-warn litigation. Doctrinal Collapse, supra note 13, at 324-25.

198. Doctrinal Collapse, supra note 13, at 313.

199. See supra notes 32-33 and accompanying text.
tled "Enterprise Responsibility for Personal Injury," was published in the spring of 1991. It briefly summarizes, among other things, some of the problems of warnings law and sets forth five "Policy Proposals" intended "to define and establish safe harbors for potential defendants." First, the Reporters' Study says, the law should retain the current rules requiring manufacturers to warn of "residual" dangers posed by well-made products and exculpating those manufacturers from liability when their warnings are adequate. Second, it proposes that a manufacturer's "[c]ompliance with specific government regulations respecting the form and content of product warnings" be exculpatory. Third, it contemplates that in evaluating the adequacy of particular warnings, courts should encourage the use of expert testimony and defer more readily to warnings "created in accordance with what are widely regarded as effective communicative techniques." Fourth, it argues that the federal government should create a "uniform national vocabulary" for information regarding risk levels. Finally, it asserts that once the manufacturer's duty to warn has been reshaped in the manner suggested by the previous four proposals, in those cases where a warning is judged inadequate, courts should adopt an explicitly pro-plaintiff presumption as to causation.

A number of these proposals closely track parts of the Henderson-Twerski thesis and for that reason will not be re-examined here. For example, in support of its suggestion that courts should encourage the use of expert testimony to evaluate warning adequacy and should defer more willingly to industry practice that employs "what are widely regarded as effective communicative techniques," the Reporters' Study explicitly cites the Henderson-Twerski argument criticized earlier in this Article. It repeats in stronger form the Henderson-Twerski argument

200. See American Law Institute, supra note 13.  
201. Id. at 70.  
202. Id.  
203. Id. Remarkably, the Report neglects to define the word "residual," even though that term is foreign to warnings discourse, and even though its ordinary meaning—"remaining" or "left over"—does not fit comfortably into the traditional vocabulary of warnings law. See Webster's New World Dictionary of American English, supra note 40, at 142.  
204. American Law Institute, supra note 13, at 72.  
205. Id. at 74.  
206. Id.  
207. Id. at 77.  
208. See id. at 74. For the criticism of the Henderson-Twerski position, see supra notes 168-99 and accompanying text. The optimism expressed both by the Reporters' Study and by the Henderson-Twerski article about the use of expert testimony at trial is misplaced. Both sets of authors seem to envision matched pairs of experts testifying to judges or lay juries about the content of the warning in question: did the manufacturer describe the "right" set of risks,
that courts should pay "more serious attention" to warning regulations established by administrative agencies. \textsuperscript{209} It also reiterates the theoretical underpinning of the Henderson-Twerski analysis: the problems of defining "obvious" and "remote" dangers, and of rationalizing a content-based approach to "adequacy," are not insurmountable, but can instead be overcome in a way that would allow the traditional doctrine to operate smoothly. \textsuperscript{210}

Two of the proposals in the \textit{Reporters' Study} differ significantly from those of Henderson and Twerski. One champions the development by the federal government of a "uniform national vocabulary" for communicating risk information and the exemption from liability of any product warning that makes "appropriate" use of this vocabulary. \textsuperscript{211} The other urges all courts to utilize an openly pro-plaintiff presumption to resolve questions of causation. \textsuperscript{212}

Although in some ways it differs significantly from the Henderson-Twerski position, the approach of the \textit{Reporters' Study} to the causation issue does not merit extended discussion here. As mentioned earlier, \textsuperscript{213} all of the approaches to causation pose problems, and none can remove the inevitably pro-plaintiff tinge of the inquiry. Since the critical difficulties with warnings law flow from the practical absence of any real limits to its "risk" and "adequacy" rules, the choice of an approach to causation is irrelevant because causation methodology is incapable by itself of erecting any meaningful limitations on the scope of those rules.

Developing a national vocabulary of risk information is much easier to propose than to accomplish. Some private groups have tried to develop small vocabularies of warning. The American National Standards Institute, for instance, has published guidelines for manufacturers of products that pose mechanical hazards, using words such as "danger,"

\begin{itemize}
\item use the "right" words for the "appropriate" audience and frame it all in the "right" format?
\item This kind of testimony is not only highly predictable but is also highly likely to confuse, rather than to assist, the average jury.
\end{itemize}

\textsuperscript{209} The \textit{Reporters' Study} proposes that manufacturer compliance with government regulations respecting the form and content of warnings be "exculpatory." \textit{American Law Institute, supra} note 13, at 72. While this stance certainly eliminates the definitional ambiguity found in the Henderson-Twerski position (regarding what constitutes "serious" consideration on the part of courts), it places consumers too much at the mercy of the administrative process, a process which is dependent for its success upon Executive and Congressional funding priorities and which has already failed the consumer in a number of glaring ways. \textit{See supra} text accompanying notes 186-95.

\textsuperscript{210} \textit{American Law Institute, supra} note 13, at 70-72.

\textsuperscript{211} \textit{Id.} at 74.

\textsuperscript{212} \textit{Id.}

\textsuperscript{213} \textit{See supra} notes 143-66 and accompanying text.
"warning," and "caution" to denote different levels of risk.\textsuperscript{214} But these proto-efforts have drawn criticism, even from authors who generally favor the development of risk vocabularies, on the ground that they are not based on "formal scientific studies of labeling efficacy."\textsuperscript{215} No one who advocates the adoption of such vocabularies seems to believe that it can be done easily. Moreover, if the federal government were to develop such a vocabulary, it would almost certainly delegate that task to one or more of the same administrative agencies whose performances thus far in the warning label area arguably leave a great deal to be desired.\textsuperscript{216} Even if those agencies could manage somehow to construct a potentially useful vocabulary of risk,\textsuperscript{217} effectively teaching it to all consumers would be tremendously difficult. For all of these reasons, linking the future of warnings law to the federal government's adoption of a national vocabulary of risk information seems neither a good nor a practical idea.\textsuperscript{218}

C. The Fundamental Shortcoming of Recent Scholarship

While the specific weaknesses in the Reporters' Study and the Henderson-Twerski article significantly undermine the force of their insights, of greater consequence than any particular analytic flaw is the misdirected perspective of each analysis. Because both view warnings law from the vantage of the traditional content or substance-based approach, neither realizes that the major obstacle to doctrinal coherence resides in that very approach.

A content-based analysis of product warnings encourages, and even requires, the detailed inspection of every aspect of the critical elements of


\textsuperscript{216} See supra notes 186-95 and accompanying text. Recently, the Food and Drug Administration proposed new regulations for labeling food products that would define words such as "light," "low-fat," "reduced," and "fresh," terms that have historically been used loosely by some manufacturers and deceptively by others. The agency will publish a final version of the regulations within a year; and the final regulations will likely become effective in two years. The proposed regulations fill a 2000 page document. See Molly O'Neill, New Rules on Labeling May Change Foods, Too, N.Y. TIMES, Nov. 13, 1991, at C1. It remains to be seen, of course, whether and to what extent consumers will learn the new vocabulary of food. But because that vocabulary deals with terms that are common to many food products, that are quantifiable, and whose meaning does not depend on either consumer experience or variations in patterns of consumer usage, it will undoubtedly be easier both to formulate and to understand than a comparable vocabulary for risk.

\textsuperscript{217} Or several such vocabularies, if the need to speak to audiences with different levels of product expertise and critically different backgrounds is as acute as earlier discussion suggested it might be. See supra notes 128-40 and accompanying text.

\textsuperscript{218} This discussion ignores the distinct but secondary problem created by this proposal: determining what constitutes the "appropriate" use of any such vocabulary.
"relevant risk" and "adequate warning." Using that analysis, courts now scrutinize each product hazard that results in a lawsuit to decide whether it should pass through the virtually non-existent filters formed in theory by the rules of obvious and remote danger.219 Because, not surprisingly, almost all claims succeed in escaping elimination at that stage of the process, courts then inspect each warning label microscopically to determine whether its particular wording, syntax, and style pass legal muster. Every risk, word, type size, and minute detail of every warning label is subject to intense judicial scrutiny.

Given this technique, which is at once heavily fact-dependent and deeply reliant on fact finders uninformed about both the science of risk and the science of communication, the resulting array of inconsistent and unreasoned decisions should come as no surprise.220 Since courts and juries lack the expertise to distinguish meaningfully among categories of risk or different styles and formats of warning labels, they are forced to draw their own necessarily idiosyncratic lines around the indeterminate concepts of "obvious," "remote," and "adequate" and to search without guidance for the "relevant" middle ground. No wonder then that, in the absence of articulable standards, different courts and juries have sketched radically different boundaries around the notions of "relevant risk" and "adequacy."

The Henderson-Twerski article and, to a lesser extent, the Reporters' Study both advance the same flawed solution to these problems. Continue to focus mostly, if not entirely, on the content of the warnings, they argue, but get the focus right. Define "obviousness" and "remoteness" in a workable fashion.221 Eliminate222 or adopt223 a pro-plaintiff presumption regarding causation. Disregard "minor differences" in the wording or format of warning labels.224 Inject "procedural rigor" into the trial of these cases.225 Have experts on both sides testify about the obviousness of the risk and the sufficiency of the warning.226 But above all, retain the current, substance-based inquiry and continue to examine word by word the content of each warning label.

These suggestions represent the triumph of hope over experience. Differences of opinion about all the key terms in warnings law are intrac-
PRODUCT LIABILITY

VII. A Tentative Process-Based Approach to Warnings Law

A. A Hypothetical Model

Because the content-based approach to warnings law has failed, courts need to replace their minute inquiries into the details of risk and adequacy with a method of analysis that focuses on the procedures used by the manufacturer prior to the adoption and publication of its warning information. If those procedures are scientifically valid, courts should adopt a rebuttable presumption that the ensuing warning label is adequate as a matter of law. If a manufacturer fails to employ such procedures, however, courts should employ a rebuttable presumption that its warning is legally inadequate.

There undoubtedly is more than one method of implementing successfully a procedural approach to failure-to-warn law. The sample methodology proposed below is meant not only to give content to this argument and to demonstrate its feasibility, but also to encourage the development of other, better methods.

Ideally, warning methodology would borrow heavily from five related fields: marketing, industrial design, injury prevention, communications, and focus group research. Almost all corporations that manufacture and sell consumer goods employ relatively sophisticated survey and interview techniques to determine which groups of consumers might buy their products and which groups do in fact buy them.227 The

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227. According to one textbook about product marketing, contemporary marketing strategy involves a number of different elements: segmentation, product, promotion, pricing, and distribution. See J. PAUL PETER & JERRY C. OLSON, CONSUMER AND MARKETING STRATEGY 11 (2d ed. 1990). Segmentation, the element most relevant to a pre-publication process...
information obtained from these techniques usually forms the basis for advertising campaigns. Manufacturers could easily use that marketing information to identify specifically the audience to whom their risk information must be directed.

Having utilized basic marketing techniques to target consumers at risk, manufacturers might then ask in-house research and design personnel, outside engineering and injury prevention experts, and consumer focus groups to explore the ranges of product use, in order to learn about those risks most likely to harm product users and most likely to for warning labels, asks which consumers are the prime prospects for the product in question and explores which particular consumer characteristics might be of greatest interest to the manufacturer. Id. at 402. Companies can choose from or among many potential "segmentation bases" for consumer markets, including the "geographic" (by region, size of locality, climate, and population density), "demographic" (by age, sex, family size, income, occupation, education, religion, race, nationality), "psychosocial" (by social class, lifestyle, and personality), and "cognitive, affective, and behavioral" (by attitudes, benefits sought, readiness stage, perceived risk, usage rate, and others). Id. at 402, 406-07; see also Robert L. Burr, Market Segments and Other Revelations, 4 J. CONSUMER MARKETING 51 (1987) (describing segmentations and target marketing of Prudential Insurance Company); Valarie A. Zeithaml, The New Demographics and Market Fragmentation, 49 J. MARKETING 64 (1985) (discussing how changing demographics and family roles may affect retailers and manufacturers).

228. For a discussion of the relationship between marketing and advertising strategies, see PETER & OLSON, supra note 227, at 478-85.

229. Knowing one's consumers is certainly useful for purposes of drafting meaningful product warnings, but not so useful as knowing which subcategories of one's consumers are more likely to be injured by one's product. Presumably, warnings specifically targeted at high-risk consumers are more likely to reduce injury than warnings directed at consumers in general. Beginning in 1972, the Consumer Product Safety Commission (CPSC) has collected data about product-related injuries, pursuant to a program known as the National Electronic Injury Surveillance System (NEISS). Using a statistical sample of hospital-based emergency departments, NEISS gathers relatively detailed reports about patients treated in the participating emergency departments, reports that name the product or products involved in the injury, and reports that describe specifically the injury itself and the relevant personal characteristics of the injured consumer. The CPSC then makes this data available to the public in various computer formats, under the terms of the Freedom of Information Act. See National Electronic Surveillance System, NEISS Data Highlights, 5 DIRECTORATE FOR EPIDEMIOLOGY 1, 1-4 (1982). The promise of this program, and the quality and quantity of the information that it gathers, have been significantly compromised in the past several years by severe Reagan-era budget cuts and staff reductions at the CPSC. See, e.g., Molly Sinclair, Inside: Consumer Product Safety Commission, WASH. POST, Mar. 10, 1983, at A17.

230. Focus groups, also called group depth interviews, are among "the most widely used research tools in the social sciences." DAVID W. STEWART & PREM N. SHAMDASANI, FOCUS GROUPS 9 (1990). Originally developed to evaluate audience response to radio programs, this interviewing technique, as its name implies, attempts to probe deeply into topics of research interest, by using a trained interviewer to direct and stimulate group discussion about those topics. The focus group interview usually involves eight to twelve people who discuss a particular topic under the direction of a trained moderator who promotes interaction among group members and assures that the discussion remains focused on the topic of interest. Id. at 10. Among the more common uses of focus groups are:

1. obtaining general background information about a topic of interest;
harm them seriously. Of course, no process can uncover every risk associated with product use, but the combination of in-house research, independent engineering expertise, injury prevention advice, and relevant consumer feedback offers the promising possibility that most of the risk territory will be canvassed.

Armed with data describing its target audiences and with a roster of relevant risks, the prudent manufacturer should next consult experts in communications science to develop appropriate wording and an adequate format for its warning label. Among other things, those experts should consider the number of risks to be mentioned, the location of the warning label, the best language to use for the target audience, the correct degree of urgency, and any other scientifically-relevant matters. Again, experts in communications science may disagree over matters of warning label content, style, and format, but the fact of professional disagreement should not by itself invalidate an honest choice among reasonable alternatives.

With this accomplished, and before sending its final warning label into the world, the manufacturer should develop a prototypical label, an experimental model incorporating its preliminary research. That model should then be tested on focus groups of identified consumers for all of the factors of wording, style, and syntax determined relevant by the communications experts. Ideally, focus group members would be asked to use the product for some period of time, thus enabling them to assess the match between the actual risks of product use and the risk information

2. generating research hypotheses that can be submitted to further research and testing using more quantitative approaches;
3. stimulating new ideas and creative concepts;
4. diagnosing the potential for problems with a new program, service, or product;
5. generating impressions of products, programs, services, institutions, or other objects of interest;
6. learning how respondents talk about the phenomenon of interest. This, in turn, may facilitate the design of questionnaires, survey instruments, or other research tools that might be employed in more quantitative research; and
7. interpreting previously obtained quantitative results.

*Id.* at 15.

While focus groups are not meant to replace all other forms of social research, they are recognized as having a number of advantages over other methods. In particular, they are “very flexible” and can be used to examine a variety of topics with a variety of people in a variety of settings. *Id.* at 16. They are also “one of the few research tools available for obtaining data from children or from individuals who are not particularly literate,” a factor of great relevance to the efficacy of product warning labels. *Id.* Furthermore, the results of focus group research are easy to understand. *Id.*

231. For a good basic description of the field of communications science and an excellent discussion of the ways in which the theory and practice of that science can be incorporated into the drafting of product warnings, see Schwartz & Driver, *supra* note 11, at 46-50.
contained on the label. If the testing process reveals consumer misunderstanding over the meaning of the label, or demonstrates that the warning information does not match actual product use, the prototype should be modified and tested again, until the manufacturer develops a version that passes muster with the focus group. Finally, to ensure that existing warning labels remain adequate, manufacturers and their communications experts should periodically test their products on new focus groups to determine whether the warning's original efficacy has been undermined by product uses not originally foreseen by the manufacturer, or by significant changes in the composition of the consumer group.

If manufacturers follow this procedure, their warning labels should be presumed adequate as a matter of law. Courts should refrain from second-guessing a scientifically acceptable process: if the process is sufficient, courts should not dissect its outcome, but should instead validate it and spare themselves the need to wrestle with the intractable dilemmas of traditional failure-to-warn doctrine. If manufacturers choose not to adopt such a procedure for developing warnings, courts should subject their warnings to an opposite and rebuttable presumption of inadequacy.

This matched set of presumptions would serve the interests of all the major actors in the failure-to-warn drama. By encouraging the use of scientifically validated procedures, courts would finally be describing for manufacturers in one of the clearest ways possible a method by which they can avoid liability. Since liability under current warnings law often seems to come randomly and almost always carries with it a large price tag, manufacturers should be quite willing to incur the costs associated with a pre-publication process in exchange for the security provided by the presumption of adequacy.

A procedural approach would also benefit consumers. While some individual consumers, who might have won damage awards under the current lottery system, will lose if the procedural methodology advocated above is adopted, the majority of consumers would receive higher quality risk information, whose efficacy and intelligibility would have passed the test of consumer focus groups, and whose continuing utility would largely be assured by periodic re-examination. To the extent that tort law seeks to deter personal injury, a doctrine that encourages manu-

232. For scholars in the law and economics movement, tort mechanisms are judged largely by the extent to which they efficiently promote the deterrence of costly outcomes. See, e.g., GUIDO CALABRESI, THE COSTS OF ACCIDENTS 16 (1970); William M. Landes & Richard A. Posner, The Positive Economic Theory of Tort Law, 15 GA. L. REV. 851, 856-64 (1981); Richard A. Posner, The Ethical and Political Basis of the Efficiency Norm in Common Law Adjudication, 8 HOFSTRA L. REV. 487, 502-03 (1980). Other writers, less convinced that the rules of tort law usually provoke rational deterrent responses by those affected, argue that the goal of compensation should predominate contemporary thinking about tort reform. See, e.g., How-
facturers to spend their dollars and energy effectively to avoid product-related harms is far better suited to consumer interests than one which compensates some consumers generously after the fact, but which does little beforehand to reduce product risk for all consumers.

Finally, a procedural approach would relieve the courts of the current necessity, imposed upon them by the flaws in existing law, of attempting to apply in a principled fashion an essentially unprincipled method of decision-making. In particular, courts could eschew the inevitably frustrating inquiries into the nature of each risk and the wording of every warning label and replace them with the simpler, more determinate examination required by the procedural approach. With that approach, outcomes in failure-to-warn cases would generally become more predictable, more consistent and more rational; substantial amounts of judicial time and energy would be saved. A doctrine that can be neither defended nor applied well would be replaced by one that is both logically defensible and capable of fair application.

Moreover, since a process-based methodology would not require manufacturers to conform to any particular procedural orthodoxy, companies would be free to devise their own effective approaches, to borrow all or parts of the useful approaches of competitors or governmental agencies, and to adjust their approaches over time, as new information or new technology might require. This flexibility is desirable not only in its own right, but especially as a counterpoise to the historical rigidity of the processes that characterize the activities of administrative agencies in the product warning field.  

Further, since investment in pre-publication warning processes will usually be economically efficient, manufacturers will almost always have clear incentives to spend money to improve those processes. Governmental agencies, by contrast, do not control the size of their budgets and are often unable, both for political and financial reasons, to devote funds continuously to warning label research and investigation.

To realize the benefits of this approach, manufacturers would need to prove, by a preponderance of the evidence, that they did in fact utilize a scientifically valid pre-publication process. For a number of reasons, proof of this fact should come in documentary form. Documents that describe the details of their procedures will best enable manufacturers to


233. See supra notes 187-95 and accompanying text.

234. That is, simply stated, the projected savings in liability avoided will exceed the costs of warning label development.
demonstrate the validity of their warning process, permit courts to decide questions of procedural validity more easily, provide plaintiffs with something tangible to challenge, and through normal channels of discovery and dissemination, help to educate other manufacturers about the state of this particular art.

Manufacturers may fear that publicly documenting their warning procedures will allow competitors to use them free of charge, but these fears can be addressed. \(^{235}\) Trade secret laws can protect proprietary processes of design and manufacture. \(^{236}\) The disclosure of warnings-related procedural information, however, will serve important public interests not implicated by trade secret laws. Furthermore, manufacturers will receive in exchange for their disclosures the benefit of presumptive legality that the procedural approach permits.

To be sure, a procedural approach to warnings law cannot repair every leak in the traditional system. Some gnawing problems will remain. In particular, it is difficult to imagine a pre-publication process that would offer a good solution to the dilemma of drafting warning information intelligible to the illiterate and the non-English reading, when those groups do not constitute a majority, or a significant minority, of the consumer group for the product in question. Some help could come in the form of appropriately informative warning and instructional tape recordings, in English and in other languages, produced after a process similar to that suggested above for written product warnings, enclosed with a product in its original packaging. Admittedly, the utility of these tapes would be limited. Some consumers, for reasons of cost or otherwise, would have no access to tape players; others, who own tape players, would find the tape-playing process sufficiently burdensome to forego the

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235. To the extent that these fears prompt manufacturers to alter their documents in order to deceive courts or competitors about either the thoroughness or the efficacy of their warning process, they will defeat the goals of the procedural approach. However, comparable fears, such as the fear of losing a trial on the merits that manufacturers currently may face under the substantive approach, might conceivably motivate them—and other litigants for that matter—to tamper with documents that have been sought as part of the discovery process, or at some other stage of litigation, but this kind of theoretical reaction to fear does not seem to have occurred much in practice.

236. See Restatement (Second) of Torts § 757 (1939). The Restatement notes that a holder of a trade secret is entitled to have it protected from misappropriation. Id. The Restatement defines a trade secret as:

any formula, pattern, device or compilation of information which is used in one's business, and which gives him an opportunity to obtain an advantage over competitors who do not know or use it. It may be a formula for a chemical compound, a process of manufacturing, treating or preserving materials, a pattern for a machine or other devices, or a list of customers.

Id. § 757 cmt. b.
use of the tape. However, in the workplace recorded warnings could have considerable value if employers incorporated them into training and orientation programs and otherwise made them readily accessible to workers not literate in English. 

Other well-established principles of tort law might provide some guidance for resolving these problems. Employers of illiterate workers, for example, could perhaps be deemed more frequently to constitute “learned or informed intermediaries” for those employees, so that in certain circumstances a procedural analysis might oblige manufacturers to demonstrate a pre-publication process directed at employers who would bear the responsibility of explaining the warning information to their workers. Non-English readers injured by products whose warn-

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237. At bottom, the problem of providing useful information about product risks to people not literate in English transcends the smaller world of products liability and poses broad cultural and political questions about the nature of effective communication in a multilingual society. Courts are not the only institutions with an interest in those questions, nor are they particularly well suited to resolve them. And though it would be terribly unfair to permit manufacturers who sell to all to ignore the informational needs of the non-English speaking, it would be equally unwise to use the courts as a testing ground for communication methodologies whose technology is unproven and whose political and cultural wisdom is debatable. Cf. Rachel F. Moran, Bilingual Education as a Status Conflict, 73 CAL. L. REV. 321, 350-39, 350-55, 357-60 (1987) (describing the acrimony and the complexity of issues that result from litigating bilingual education suits).

238. The learned-intermediary doctrine is a judge-made rule developed to ameliorate certain practical warning problems confronting the manufacturers of prescription drugs. Thus, while those manufacturers have traditionally had a duty to warn about the dangerous side effects and risks associated with the use of their products, see, e.g., Lindsay v. Ortho Pharmaceutical Corp., 637 F.2d 87, 91 (2d Cir. 1980); McEwen v. Ortho Pharmaceutical Corp., 270 Or. 375, 385-90, 528 P.2d 522, 528-30 (1974), in many jurisdictions manufacturers can satisfy that duty by providing the requisite warning to the prescribing physician alone, see, e.g., Hoffman v. Sterling Drug, Inc., 485 F.2d 132, 142 (3d Cir. 1973); McCue v. Norwich Pharmacal Co., 453 F.2d 1033, 1035 (1st Cir. 1972), and can properly assume that since the patient/consumer cannot obtain prescription drugs without the physician’s authorization, the informed physician will have an opportunity to describe to the patient, in a manner presumably geared to the patient’s level of comprehension, the risks attendant upon the use of the manufacturer’s product. See Polley v. Ciba-Geigy Corp., 658 F. Supp. 420, 421 (D. Alaska 1987).

One way of describing the operating assumption of the learned intermediary doctrine would suggest that when the ultimate user of a product can obtain it only through some third person the product’s manufacturer can lawfully direct its warning to that third person and rely on that party’s fiduciary or other duties to insure that the ultimate consumer receives the necessary warning information. Many employees gain access to the products that they use at work solely by virtue of their employment. Since employers are required to provide their employees with a safe workplace, see Occupational Safety and Health Act of 1970, 29 U.S.C. §§ 651-678 (1988), and can or should be institutionally capable of understanding product warnings and communicating them to their workers, the learned intermediary doctrine could arguably apply, without too much strain, to require employers to advise their illiterate employees of the risks of using products supplied or made available to them in connection with their work.

239. The process-based approach might require, for example, that manufacturers, in conducting their marketing analyses, research the composition and literacy levels of the
ing labels are written only in English might properly be regarded as contributory or comparatively negligent for having undertaken an activity the risks of which they did not fully understand. But both of these solutions are unsatisfying, legally as well as politically. The former, by replacing a manufacturer's duty with an employer's, would remit to the confined world of workers' compensation law a type of claim that previously had been unconstrained by damage schedules, while the latter would result in the grim prospect of offering to disadvantaged groups fewer of the protections afforded by the law to more favored segments of the population.

Indeed, the procedural approach encounters problems when the consumer group for a particular product is diverse. Assuming that its warning label might need to alert different user groups to different risks, and given the physical and scientific constraints on warning label size, workforce of their employer-customers and work with those customers to develop programs that explain product risks directly to the employees. For an interesting discussion of how, in certain circumstances, the "learned intermediary" doctrine might require a chain of warnings, stretching from the manufacturer to groups of more sophisticated users, and from those groups to others having little or no experience with the product in question, see Kenneth M. Willner, Note, Failures To Warn and the Sophisticated User Defense, 74 VA. L. REV. 579, 590-96 (1988).

240. Contributory negligence is generally defined as "conduct on the part of the plaintiff, contributing as a legal cause to the harm he has suffered, which falls below the standard to which he is required to conform for his own protection." W. PAGE KEETON ET AL., supra note 91, § 65, at 451. Unlike contributory negligence, which acts as a complete bar to plaintiff's recovery, comparative negligence assigns relative degrees of fault to all plaintiffs and defendants, and then apportions damages on the basis of the relative distribution of fault. Id. § 67, at 470-77.

241. In all states, workers' compensation laws provide to employees injured in the course of their employment an exclusive statutory remedy against their employers, pursuant to a scheme that first categorizes injuries (temporary partial, temporary total, permanent partial, and permanent total) and then establishes schedules of compensation levels appropriate for each type of injury. See 1C ARTHUR LARSON, THE LAW OF WORKMEN'S COMPENSATION § 58 (1992); 2 LARSON, supra, at §§ 59-60; 4 ARTHUR LARSON, THE LAW OF WORKMEN'S COMPENSATION app. B, tables 8, 9, 16 (1990).

242. The potential incentives that these solutions create are of dubious utility. They "tell" illiterates, for example, to learn to read, a message that has doubtless been sent before, and whose reiteration does nothing to facilitate the task of learning to read. At bottom, the establishment of universal literacy seems more a governmental obligation than a private one. Using the tort system to induce illiterates to learn to read probably sends a message that is not only redundant but that is frustrating as well, since for many illiterates there may be no practical way to achieve literacy. For the non-English reading, the judicial message strongly encourages literacy in English. While this is doubtless a useful skill for residents of this country, to compel its adoption through the tort system runs a serious risk of tampering with delicate political and cultural questions about ethnic identity, cultural heritage, and linguistic preservation that are perhaps best resolved in other institutional arenas. For a provocative discussion of the issues of power, politics, and culture raised over the past 20 years in the conflict between the "English only" movement and groups favoring bilingual education, see Moran, supra note 237, at 326-33, 339-41.
should the manufacturer direct the warning to a hypothetical "average" consumer or to the largest subgroup of consumers? These kinds of problems are truly intractable, not just for a process-based methodology but for any approach to warnings law. Faced with this dilemma, the current content-based approach almost always decides that the manufacturer should have added more risk information to its warning, but never decides—never can decide—when this process of addition should stop. A procedural approach to this problem would presumably permit manufacturers to use their demonstrably well-informed and scientifically verifiable discretion to make the hard choices necessitated by the constraints of space and user comprehension discussed above.

Finally, in cases where manufacturers choose not to avail themselves of any pre-publication process, a procedural approach would require courts to adopt a rebuttable presumption that the warning in question was inadequate as a matter of law. This aspect of the approach would serve four distinct purposes. First, it would spur manufacturers to employ useful procedural methodology and to extend its benefits to a larger number of consumers, thus advancing the important goal of injury prevention. Second, if manufacturers decide against using that methodology, courts would then possess a more rational basis for imposing liability on them: Having spurned valid procedures, manufacturers reasonably can be made to face the failure-to-warn claim at their peril. Third, a clearly articulated pro-plaintiff presumption in this class of cases would sometimes make evident what courts now frequently attempt to hide: Injured plaintiffs in warnings cases are a favored class. Making this bias explicit, especially when there are good reasons for doing so, would represent an act of judicial honesty that would enhance popular respect for the system. Lastly, the use of this second presumption would arguably permit courts to decide many cases more quickly than otherwise, and thus would contribute significantly to the efficient administration of justice.

B. The Procedural Approach, Alternate Vocabularies, and the Question of Relative Indeterminacy

In large measure, a procedural approach to warnings law is necessitated by the problems of linguistic indeterminacy that plague existing doctrine. In the course of addressing those problems, however, the

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243. See supra notes 198-99 and accompanying text.
244. See supra notes 150-55 and accompanying text.
245. See supra notes 38-70 and accompanying text (discussing the linguistic indeterminacy inherent in the obvious-danger rule); supra notes 71-83 and accompanying text (discussing the linguistic indeterminacy inherent in the remote-danger rule).
procedural approach raises three philosophically related questions about the arguably inherent insufficiency of language, both in warnings law in particular and in torts law in general.

One might concede, for example, that the present terminology of warnings law is hopelessly indeterminate,246 and nevertheless argue that the cause of that indeterminacy is not to be found in the existing substantive approach, but rather stems from an historically "poor" choice of a working vocabulary for elaborating that approach. Perhaps, in other words, a "better," less subjective, vocabulary of risk would enable the existing approach to yield more coherent results in warnings cases, and would obviate the need for a major change in judicial methodology. Further, one might admit that the deficiencies of its vocabulary doom the substantive approach to produce an irrational and incoherent body of law, but contend that shifting to a procedural methodology would accomplish little in the way of rationalizing warnings law, since the language of the new approach could be no more determinate than that of the old. Finally, while one might be willing to acknowledge that terms like "obvious" and "adequate" cannot often be put to good use in warnings law, one might caution against abandoning them, for fear of descending the slippery slope; if we jettison those words, then must we not also discard other elements of the torts lexicon, words like "reasonable" and "necessary," for example, that must be equally devoid of articulable meaning? And, having shed all of that vague terminology, will we find anything left of the linguistic structure of tort law or will we have deconstructed it into oblivion?

A yearning for a more determinate vocabulary lies at the heart of the Reporters' Study's proposal that the federal government "create a uniform national vocabulary . . . respecting risk levels."247 But even if such a vocabulary could be developed and communicated effectively—tasks of no small order248—the problem of selecting which kinds of risks merit description by the new vocabulary would remain the central question of warnings law. As long as the courts answer that question by reference to the empty notions of "obvious" and "remote," resolution of that problem will continue to be stalled in semantic gridlock.

Since the existing approach to failure-to-warn claims always starts, and usually ends, by characterizing the hazard in question as either "obvious," "remote," or "relevant," it offers no escape from the problems inherent in defining undefinable terms. Courts laboring under the pre-

246. See supra notes 14-89 and accompanying text.
247. See AMERICAN LAW INSTITUTE, supra note 13, at 74.
248. See supra notes 214-18 and accompanying text.
vailing methodology will continue to need terminology that limits the manufacturer's warning obligation to some "reasonable" dimension, unless they are prepared instead to announce that manufacturers must warn about all product risks of which they know.  But since any language intended to distinguish legally "relevant" risks from legally "irrelevant" ones will inevitably recreate the subjectivity characteristic of the "obvious" and "remote" tandem, acute problems of indeterminacy seem unavoidable in any substance-based approach to warnings law.

But if indeterminacy is bound to infect a warnings doctrine that focuses on substance, why, one might ask, would it not have the same harmful impact on a process-based approach? Indeed, if all words are equally indeterminate, there is no good answer to this question. Not all words, however, seem to share the same degree of indeterminacy. Compared to the words "obvious," "remote," and "adequate," the critical terminology of the procedural approach described above seems fixed and objective. Expert testimony can define for a court the terms "focus group" and "market research," for example, at least within bounds that seem capable of reasoned expression and useful debate. Deciding whether a manufacturer took the relevant procedural steps—yes or no—is more or less verifiable, and infinitely easier than arriving at a broadly applicable understanding of the key words of current doctrine. If, then, determinacy is relative, and more determinacy is better than less, the procedural approach advocated in this Article is preferable on linguistic grounds to the current terminology of warnings law.

One still might ask, even if determinacy is relative, and even if the language of "scientific" procedures is arguably more objective than the open-ended adjectives that form the core of the traditional vocabulary of warnings law, how can we criticize words like "obvious" and "adequate," without also calling into question terms such as "reasonable" and "negligent," and thereby threatening to topple the entire semantic framework of torts? One might suggest that it is preferable to indulge ourselves in a philosophical fiction and profess to understand the meaning of "obvious" and "adequate," closing our eyes to the fundamental problems of warnings law, so that we also can continue pretending to understand what "reasonable" means and forestall the need to challenge the rationality of the bulk of torts law.

Such an elaborate fiction, however, and its attendant self-deception

249. As discussed earlier, supra notes 93-96 and accompanying text, such a rule would not only be physically impossible for many manufacturers to satisfy, but would also present consumers with problems of informational overload.

250. Nor, for that matter, will there be a good answer to any other question, since no question will be capable of being either well understood or well answered.
are unnecessary, because in this context, "reasonable" can indeed be distinguished from "adequate." A discussion of the many ways in which torts law defines the term "reasonable" is well beyond the scope of this Article. Suffice it to say that some notion of "reasonable" behavior, or of the "reasonable" person, instructs the development of the duty concept in a great many tort actions. What distinguishes those actions from failure-to-warn claims, though, and what argues strongly for the existence of a functional distinction between "reasonable" and "adequate," is that warnings cases are, unlike the others, neither local nor relational in character. The large majority involve national or regional manufacturers selling to people whom they have never met.

Most tort actions are arguably either local or relational, with defendants falling into one of two categories. In the first category are those defendants who were linked with the plaintiff, prior to the accident, in a relationship, contractual or quasi-contractual, that gave rise to a duty of care. In the second category are those who have allegedly failed to

251. That notion, first expressed as the concept of the prudent man, was adopted in Vaughan v. Menlove, 3 Bing. (N.C.) 468, 472-75, 132 Eng. Rep. 490, 492-93 (1837), as the standard for negligence. Id. Over time, it has been personified by a number of different characters, e.g., "the man in the street," or "the man who takes the magazines, at home and... pushes the lawn mower in his shirt sleeves." Hall v. Brooklands Auto Racing Club, [1933] 1 K.B. 205, 224. It has remained the defining standard of conduct in negligence cases. See, e.g., KEETON et al., supra note 91, § 32, at 173-75.

252. Commentators have consistently recognized, for example, that the reasonable person standard requires courts and juries to assess the defendant's conduct by defining "reasonable" according to their community's understanding of what constitutes proper behavior. See, e.g., KEETON et al., supra note 91, § 32, at 173-75; Fleming James, Jr., Nature of Negligence, 3 UTAH L. REV. 275, 280 (1953); Fleming James, Jr., The Quality of the Reasonable Man in Negligence Cases, 16 Mo. L. REV. 1, 1-2 (1951); Osborne M. Reynolds, Jr., The Reasonable Man of Negligence Law: A Health Report on the "Odious Creature," 23 OKLA. L. REV. 410, 423-24 (1970) ("[W]e use a jury... so that we may obtain the community's judgment of what is proper... If we broaden the meaning of community to take in a wide area... we are back to our average man.").

253. Many kinds of relationships give rise under the law to duties of care. A wide variety of contractual or quasi-contractual arrangements such as those, for example, between bailor and bailee, host and guest, owner and invitee, landlord and tenant, doctor and patient, or lifeguard and swimmer, may create such duties. See generally RESTATEMENT (SECOND) OF TORTS § 314A (1965) ("Special Relations Giving Rise to Duty to Aid or Protect"). Duties are also created by certain "special" relationships, so-called because one party's superior knowledge or voluntary undertaking is found to occasion toward the other a duty of care that would not otherwise exist. See, e.g., Tarasoff v. Regents of Univ. of Cal., 17 Cal. 3d 425, 450, 551 P.2d 334, 353, 131 Cal. Rptr. 14, 33 (1976) (finding that psychotherapist who determined that his patient planned to kill a specific individual had a duty to protect the intended victim); Morgan v. County of Yuba, 230 Cal. App. 2d 938, 941-44, 41 Cal. Rptr. 508, 510-12 (1964) (holding that sheriff, who had promised to inform plaintiff about the release from jail of a prisoner who had threatened her, was negligent for having failed to do so). See generally RESTATEMENT (SECOND) OF TORTS § 314A cmt. b (1965) (noting that "[t]he law appears to
observe either express\textsuperscript{254} or implicit\textsuperscript{255} norms of local behavior. For purposes of this discussion, these two categories of cases share two extremely important characteristics. In each, the notion of reasonableness is contextually bounded, either by the terms or expectations of a relationship formed in the community, or by community experience with the behavior in question. The remedy in each is also local, involving either the payment of damages and nothing more or the alteration of a behavior whose scale was relatively confined.

Warnings law is different. A nominal relationship exists between the maker of a product and its buyer, but because manufacturers cannot know all of the people who use their products, rarely contract with them directly, and never learn their specific informational needs, the relationship lacks content.\textsuperscript{256} Indeed, warnings must be directed not just to product buyers, but to product users as well, a much larger category of potential plaintiffs, and one without even a nominal relationship to the manufacturer. For most products, moreover, the drafting of a warning label is a quintessentially national activity. Since almost all products are portable and capable of being moved frequently from one locality to an-

\textsuperscript{254} The doctrine of negligence per se, for example, is predicated upon the defendant's violation of a particular statute or local ordinance. \textit{See generally RESTATEMENT (SECOND) OF TORTS} § 288B (1965) (addressing the effect of an unexcused violation of a legislative enactment). \textit{See also CONN. GEN. STAT.} § 14-80h (1990) (stating that failure to have brakes in condition required by statute constitutes negligence per se); Hendrix v. Miller, 287 Ala. 486, 491, 252 So. 2d 640, 645 (1971) (holding that violation of local traffic ordinance is negligence per se); Baker v. Mauldin, 82 N.C. App. 404, 406, 346 S.E.2d 240, 241 (1986) (stating that operating vehicle while under the influence of intoxicants is negligence per se).

\textsuperscript{255} In many ways, the common-law action of nuisance is the paradigmatic local tort. A private nuisance is defined generally as a substantial and unreasonable interference with one's use and enjoyment of his land, \textit{see KEETON et al., supra} note 91, § 87, at 619, while the concept of public nuisance extends more broadly to almost any form of obstruction or inconvenience that burdens the use of common public rights. \textit{Id.} § 86, at 618. Both doctrines, however, rely in their application entirely upon individuated community notions of appropriate conduct. For the application of community standards to private nuisances, see \textit{RESTATEMENT (SECOND) OF TORTS} § 821D (1965) (citing Wade v. Miller, 188 Mass. 6, 7, 73 N.E. 849, 849 (Mass. 1905) (deciding that in this particular town, odors and noises of poultry were not offensive to ordinary citizens and therefore not a nuisance)); and, as to public nuisance, see \textit{RESTATEMENT (SECOND) OF TORTS} § 821B (1965) (citing Village of Euclid v. Ambler Realty Co., 272 U.S. 365, 388 (1926) ("A nuisance may be merely a right thing in the wrong place, like a pig in the parlor instead of the barnyard."); Richard A. Epstein, \textit{Nuisance Law: Corrective Justice and Its Utilitarian Constraints,} 8 J. LEGAL STUD. 49, 87-90 (1979).

\textsuperscript{256} Contrast this situation with the doctor-patient relationship, the only other instance where the common law requires an affirmative and detailed exchange of information between "more knowing" and "less knowing" parties. \textit{61 AM. JUR. 2D Physicians, Surgeons, and Other Healers} §§ 166-167 (1981). Doctors have intimate, first-hand experience with their patients, the ability to speak with them directly in a controlled setting, and the opportunity to tailor their message to the perceived needs of the patient.
other, companies must draft one, and only one, warning for each of their products. Unlike product design, marketing, and sales efforts, which can often reflect local or regional factors, warning labels are inflexible, necessarily saying the same thing to everyone in the country.

Because failure-to-warn cases are neither local nor relational, judges and juries are ill-equipped institutionally to assess the content of particular warnings. Manufacturers cannot usefully speak to all local or relational needs, since they cannot, economically or safely, draft warnings specially designed for each product user or each community. Nor can courts or juries impose remedies that are local or relational in scope. By compelling a change in the "local" label, a judgment that a particular warning is "inadequate" inevitably forces a change in the "national" label as well, regardless of whether it is generally wise to effect such a change. In other words, warnings cases unmoor local decision-makers from the contexts in which questions of "reasonableness" can be usefully answered, place them in the position of judging the "reasonableness" of activity that cannot be taken with only them in mind, and enable—indeed, compel—them to engrat parochial solutions onto ecumenical problems. Because it requires factfinders to make non-contextual decisions about ambiguous terms, the language of warnings law is unworkable in a way that most of torts law is not.257 For this reason, changing the analytic paradigm in warnings law will neither unravel the rest of torts law nor force us to view "reasonableness" in make-believe fashion.

C. Some Current Analogies to the Process-Based Approach

If courts were to adopt the procedural approach described above, failure-to-warn law would not be the first to consider or utilize a form of process-based methodology. Not only do medical malpractice law and administrative law employ distinctly procedural methodologies, but some commentators have already advocated the use of a process-oriented analysis for certain other aspects of products liability law.

Consider first the area of medical malpractice. The liability inquiry in that area focuses not on whether the defendant failed substantively to improve the plaintiff's health, for example, but on whether she failed

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257. In some sense, this discussion about the difference between warnings law and other areas of torts law that employ a reasonableness standard is less about linguistic determinacy and more about linguistic context. That is, the current approach to warnings law inevitably requires the use of terms like "obvious" and "adequate" and asks juries to infuse them with local, individualized definitions which are then employed to judge the legality of a national endeavor usually aimed at the "average consumer." Under these circumstances, if the words were switched—if warnings had to be "reasonable" and other behavior had to be "adequate," for example—"reasonable" would fail and "adequate" would succeed.
procedurally, by neglecting to follow a scientifically valid treatment methodology. Moreover, the procedural standard of care adopted by most courts depends for its efficacy upon some notion of scientific validity whose elaboration is itself dependent upon expert testimony from members of the defendant's profession.

For many years, a physician's liability for alleged medical malpractice has hinged not upon whether her patient suffered a substantively "bad" outcome from a medical intervention, but upon whether the physician employed procedures and techniques that were scientifically "reasonable" or "acceptable." In the late 1950s, medical malpractice doctrine regarded "compliance with accepted practice" as the conclusive benchmark of proper care and permitted evidence of local medical custom, established through the testimony of local physicians, to define the scientific standard. Over the past thirty years, that narrow standard has expanded dramatically and has evolved into a much broader construct that considers a variety of approaches to be scientifically valid. Admittedly, that evolution has resulted neither in judicial


259. With a few minor exceptions, the standard of care in medical malpractice cases has historically been provided by expert medical testimony. See Allan H. McCoid, The Care Required of Medical Practitioners, 12 VAND. L. REV. 549, 560 (1959); Jon R. Waltz, The Rise and Gradual Fall of the Locality Rule in Medical Malpractice Litigation, 18 DEPAUL L. REV. 408, 409 (1969).


261. See McCoid, supra note 259, at 558.

262. Both aspects of the so-called "locality rule"—that local procedures, as described by local doctors, formed the legal standard—have been almost completely eroded by recent case law. See Shilkret v. Annapolis Emergency Hosp. Assoc., 276 Md. 187, 199, 349 A.2d 245, 252 (1975); Hall v. Hilbun, 466 So. 2d 856, 871-72 (Miss. 1985); Pederson v. Dumouchel, 72 Wash. 2d 73, 79, 431 P.2d 973, 978 (1967).

263. See McCoid, supra note 259, at 605-09 (discussing customary practice as "almost exclusively, the measure of due care"); see also Waltz, supra note 259, at 410-11 (describing the early form of the locality rule that required testimony from an expert who came from the same town as the defendant).

264. There are at least four different, acceptable standards. Where scientific authority is divided about the wisdom of a particular procedure, the "respectable minority" standard permits a physician to follow a method of treatment advocated by a "considerable number" of physicians in his or her area of practice. McHugh v. Audet, 72 F. Supp. 394, 400 (M.D. Pa. 1947); see also Chumbler v. McClure, 505 F.2d 489, 492 (6th Cir. 1974) (holding that it is not malpractice to be among the minority in a given city who follow one of the accepted schools where two or more schools of thought exist among competent medical professionals); Leech v.
unanimity about the correct methodology, nor in outpourings of academic praise for the coherence of medical malpractice law. Nevertheless, it has proven the vitality and adaptability of an approach that looks less to the substantive character of the alleged wrong and more to its procedural aspects. Thus, despite suggestions that the entire fault-based system of medical malpractice be scrapped in favor of a regime of strict liability, the existing procedural approach endures, suggesting at least that an analogous approach to warnings claims might also survive.

Not only has medical malpractice law made arguably good use of a procedurally-focused inquiry, it has done so despite the seeming difficulties of defining scientifically acceptable procedures and of relying for those definitions upon the expert testimony of members of the defendants' profession. Different courts have arrived at differing notions of "valid" procedure, but without creating the kind of critical uproar recently aimed at failure-to-warn doctrine. Thus, while commentators decry the "acute . . . problem of partisan experts" in malpractice cases,
even proposals to modify the system do no more than suggest the increased use of impartial medical expertise. At least in this context, the courts have largely resolved the problem of determining "scientific validity," a fact that bodes well for the success of a procedural approach in the failure-to-warn area.

Consider next the example of administrative law. Over the past twenty-five years, a combination of complicated new federal statutes aimed at protecting the environment and Reagan-era deregulation has engendered a revolutionary shift in the premises underlying judicial review of agency action. Appellate courts that had traditionally deferred to agency rulemaking began, in the 1970s and 80s, to drop their deferential ways and to engage instead in what has come to be called "hard-look review." This form of review generally requires appellate judges to be more demanding in their scrutiny of agency action and to make more probing inquiries into the factual determinations and procedural steps that formed the predicate for that action.

Shortly after the initial articulation of "hard-look review," a schism developed between two of its principal proponents, Judges Leventhal and Bazelon of the United States Court of Appeals for the District of Columbia. Judge Leventhal insisted that courts must familiarize themselves with the factual underpinnings of agency action, no matter how compli-

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268. See Fed R. Evid. 706 (authorizing the courts to appoint impartial experts, whose costs would be chargeable to the parties).


270. One court has described "hard look" review as requiring a standard of appellate evaluation designed to test whether the agency in question has reasonably considered all of the material facts and issues; whether it has, in other words, taken a hard look at those issues; and whether it has articulated the basis of its decision with reasonable clarity, identifying those facts thought to be significant or crucial to its decision. Greater Boston Television Corp. v. FCC, 444 F.2d 841, 850-53 (D.C. Cir. 1970), cert. denied, 403 U.S. 923 (1971). For two other cases that outline the history and rationale of this development, see Ethyl Corp. v. EPA, 541 F.2d 1, 33-36 (D.C.Cir. 1975), cert. denied, 426 U.S. 941 (1976); See Citizens to Preserve Overton Park, Inc. v. Volpe, 401 U.S. 402, 416 (1971).

icated those facts might be, because it was only through such familiarity that they could secure rational agency outcomes. Judge Bazelon, by contrast, cautioned against a deeply substantive form of review, arguing that judges lacked the technical expertise necessary for engaging in the detailed examination of complicated scientific matters, and advocated instead an appellate stance intended to assure that the agency had carefully followed an appropriate set of procedures.

The Leventhal-Bazelon debate about the appropriate scope of "hard-look review" has proved a natural stimulant to academic discussion of the topic. While some commentators have argued for an expanded, substantive inquiry into the wisdom of regulatory decisions, others have called for an approach that emphasizes process and avoids extensive content-based examinations into matters within the agency's area of expertise.

Although the dispute over the proper standard of review in administrative law is not settled, by now its arguments have been well rehearsed. The "Leventhal" school contends that, either because of capture, ineptitude, or particular political agendas, agencies often make substantively incorrect decisions, and that only aggressive courts, willing to examine in depth the substance of those decisions, can spare us their untoward consequences. The "Bazelon" school, by contrast, questions the expertise, political propriety, and efficiency of a substantive approach to judicial review and argues that while courts are quite competent to resolve issues of procedure, their institutional competence stops where questions of substantive expertise begin.

The procedural approach outlined in this Article reflects the same kind of discomfort with traditional decision-making processes that informs the debate about the proper scope of judicial review of agency determinations. Indeed, the process-based approach described above shares some of the same shortcomings attributed to the Bazelon school of "hard-look review." Like that standard, a procedural approach to warn-


273. See, for example, the opinion of Judge Bazelon in Ethyl Corp., 541 F.2d at 66.


276. Sive, supra note 274, at 650-51.

277. Ethyl Corp., 541 F.2d at 66 (Bazelon, J., dissenting).
ings law is vulnerable to the criticism that it may result in incorrect or unfair decisions, may fail to afford sufficient protection to consumers, and may leave serious injury uncompensated. But it also contains the virtues of that approach. Courts are asked to do what they do best: evaluate procedural fairness. Technical expertise is encouraged and given its due. A judicial focus on method is used to shape outcomes that not only are broadly beneficial to consumers, but are also fair to other participants in the process and capable of reasoned explanation by the courts.

Finally, the approach advanced in this article has an historical antecedent much closer to home. Twelve years ago, Professor Twerski and three colleagues proposed that defendants in design defect litigation have at their disposal a process defense. Specifically, they suggested that "[i]f a manufacturer defends an action by revealing a well-documented safety review process, the court should presume that the product is not defective." Ironically, in light of Professor Twerski's more recent endorsement of heightened attention to agency rules regarding warnings, his process thesis for design cases stemmed in part from a multi-faceted distrust of the competence of federal agencies. Curiously, from the perspective of failure-to-warn law, he explicitly rejected the idea that his procedural approach could be applied with equal efficacy to issues of warning label adequacy.

Twerski and his co-authors failed to recognize the havoc wreaked on warnings law by the irresolvable ambiguity of its critical terms, a failing that seriously distorted their view of warnings issues. By realizing, how-

279. Id.
280. See supra notes 186-97 and accompanying text (discussing and criticizing Professor Twerski's proposal).
282. Twerski et al., supra note 278, at 381. The reasons for that rejection are not made perfectly clear, nor do they seem correct, even on their own terms. Thus, the authors argue that "the failure-to-warn problem is less polycentric 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." Id. In other words, the various elements of an "adequate" warning lack the same high degree of interrelatedness possessed by the elements of product design. For reasons expressed earlier, this author disagrees with that conclusion, to the extent that it implies that judging the adequacy of warning labels does not present courts with intractable problems of polycentricity. See discussion supra note 140. To the extent that it purports to measure relative degrees of polycentricity, this author does not understand it. And to the extent that it ignores the problems of linguistic indeterminacy that completely frustrate doctrinal coherence, this author is critical of it.
ever, that a process-based approach could rationalize the law of design defects, they broke important theoretical ground. The idea of a procedural approach is thus no longer new to products liability law. On Twerski's terms, "correctly" applied, process-based methodology makes good sense for warnings law. On this author's terms, procedural analysis is its last hope.283

D. Is Strict Liability a Viable Alternative?

Simply because the existing content-based approach to warnings law cannot work, a process-based technique may not be the best alternative. A procedural methodology, after all, would attempt to correct some of the pro-plaintiff biases found in the current system and would give it a decidedly pro-defendant cast. Why not, some might argue, turn the system more forcefully in the other direction, admit that it has become essentially a vehicle for plaintiff compensation, and transform it into a regime of strict liability?

Indeed, on the most general of levels, a scheme of strict liability for warning-related injuries might seem to respond directly to many of the systemic problems of the current approach. In place of the prevailing confusion, a rule of strict liability would substitute a new certainty. Warnings law would be driven by the goal of plaintiff compensation.284 Deterrence would be provided by an intimidating regime of liability without fault. Finally, the costs to the manufacturer of this new regime, the costs of drafting "perfect" warnings and of insuring against the consequences of imperfect ones, would be internalized and passed on equitably to all product users, much in the manner of strict liability for product

283. There is no denying the breadth and intelligence of Professor Twerski's work in products liability law generally, or in the failure-to-warn area in particular. In addition to the 1980 article under discussion, see Obvious Danger Warnings, supra note 32; Doctrinal Collapse, supra note 13; ALVIN S. WEINSTEIN ET AL., PRODUCTS LIABILITY AND THE REASONABLY SAFE PRODUCT (1978); Use and Abuse of Warnings, supra note 11. But his scholarly peregrinations around some of the more difficult issues in warnings law symbolize the intractability and futility of current doctrine. Thus, in his "process" article in 1980, Twerski was a staunch foe of the administrative process, see Twerski et al., supra note 278, at 352-55, but today he champions its increased use. See Doctrinal Collapse, supra note 13, at 320. In that same 1980 piece, Twerski and his co-authors found the problems of product warnings "less polycentric" than those of product design, id. at 381, although just four years earlier they had concluded that a warnings case is "every bit as complex and can involve the same elements of polycentricity" as a classic design case. See Use and Abuse of Warnings, supra note 11, at 525.

Whatever the seeming merits of a proposal for a rule of strict liability, however, the practical implications of such a rule argue overwhelmingly against it. Three separate kinds of "strict" regimes seem possible. The first, which would impose liability upon a manufacturer for all product-related injuries, regardless of its fault, would totally reshape all the components of current products law and completely remove from the liability calculus any consideration of the manufacturer's conduct or the user's responsibility. As a response to the dilemmas of warnings law, it seems far too extreme.

The second, a Beshada-like approach, would oblige manufacturers to provide consumers with "adequate" warnings about all "relevant" product risks, even those that were unknowable at the time that the product was marketed. The "strictness" of this type of methodology, however, has been widely criticized as irrational, since it not only punishes manufacturers for failing to perform the impossible, but also skews their incentives to engage in an efficient amount of safety research and either severely disrupts or totally eliminates a significant portion of the insurance market for products liability. Offered and rejected, this version of strict liability is an idea whose time has passed.

The third, and more moderate, regime would be a rough analogue of the existing rule for manufacturing defects. Under that rule, a plaintiff seeking recovery for an injury allegedly caused by a product defect must show only that the product was in fact defective when placed on the market, and that the defect actually caused his injury. He need not prove that the defect resulted from the defendant's negligence. A strict approach for warnings might provide, in parallel fashion, that when a plaintiff's injuries are brought about by a defect in the defendant's warn-


286. For a discussion of Beshada and its progeny, see supra note 87.


The plaintiff can recover without having to demonstrate negligence in the preparation of the warning.

Once this hypothetical rule of strict liability is articulated, however, it becomes apparent that it precisely describes the present state of affairs in warnings law. Indeed, a number of courts have expressly remarked upon the almost perfect similarity between the negligence and strict liability approaches to warnings claims. If anything, because of its relaxed view of causation, existing failure-to-warn law may be even more “strict” than the theoretical model. This means either that a conscious shift to an explicit rule of strict liability would be redundant, because prevailing methodology is sufficiently strict, or that the institution of a strict liability approach would solve none of the mysteries of current warnings law, since it would still require courts to engage in the same futile and anarchical search for “defect”—whether the “relevant” risk was enumerated and whether the warning label otherwise was “adequate”—that lies at the root of existing doctrinal ills.

Moreover, one of the rationales traditionally invoked in support of strict liability is the compulsion that it exerts on manufacturers to redress contractually irremediable imbalances of information. By concentrating on the process by which the manufacturer gathers and uses risk information, the procedural approach advocated in this Article undertakes, first, to persuade manufacturers to employ rational and scientific methods for amassing risk information and, ultimately, to permit them to jus-

289. A “defective label,” for this purpose, would be one that failed to alert the consumer to a relevant risk of injury that was scientifically knowable to the manufacturer at the time that its product was marketed.

The issue of what degree of scientific knowledge must exist in order to invoke the duty to warn, which is beyond the scope of this article, is itself a fascinating topic. For example, in Finn v. G.D. Searle & Co., 35 Cal. 3d 691, 677 P.2d 1147, 200 Cal. Rptr. 870 (1984), the California Supreme Court suggested that a legal test that focused on scientific “knowledge” was misdirected, since “knowledge,” in the sense of absolute certainty, might never exist as to particular risks. Id. at 701, 677 P.2d at 1153, 200 Cal. Rptr. at 876. Because the causal link established by science “may range from extremely vague to highly certain,” courts should attempt to define the duty to warn by describing the strength of the scientifically sufficient causal connection. Id. at 699-701, 677 P.2d at 1152-53; 200 Cal. Rptr. at 874-876. Whether knowledge, in the relevant sense, is a quantitative term (10, 15, 20 studies, for example) or a qualitative one (one article in the “best” journal) is an open question.


tify their actions by relying on procedures designed to meet the informational needs of their consumers.

VII. CONCLUSION

The trade-offs are clear. While current doctrine offers more consumer recovery after the fact, it provides little injury prevention beforehand. While it affords judges and juries greater discretion in dealing with ever-varying factual patterns, it furnishes them with no real standards or meaningful criteria to apply to those patterns. While it permits at least the piecemeal alteration of warning labels that have failed to alert consumers to relevant risks of product use, it places manufacturers in a hopeless quandary over how to satisfy a warning requirement the contours of which have not and cannot be revealed.

Failure-to-warn law needs a major overhaul. It is a doctrinal body with almost no working parts. The procedural approach outlined in this article will not cure all of the problems in the law, but it will ameliorate the major ones, while at the same time advancing the interests of consumers in injury prevention, the interests of manufacturers in judicial guidance and predictability, and the interests of courts in rational, coherent, and efficient jurisprudence.