Risk-Utility Analysis in the Failure to Warn Context

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Elsewhere in this Symposium issue, Professor Mark Geistfeld presents an argument favoring the application of risk-utility analysis to the duty to warn doctrine encompassed by the Restatement (Third) of Torts. In addition, the comments and the reporters' notes to the Restatement (Third) suggest altering the traditional duty to warn if the warning would cause "information overload," if the danger is "open and obvious," or if the danger applies to only a small percentage of potential customers.

In response to Geistfeld and the Restatement (Third) comments and notes, Rheingold and Feinglass assert that applying a risk-utility analysis or altering the duty to warn in certain cases undermines the doctrine and does not reflect the application of the doctrine by the courts. Instead, Rheingold and Feinglass argue that the traditional duty to warn doctrine should remain the focus of the Restatement (Third). The authors point to the text of the Restatement (Third); the potential difficulties in determining the utility of a warning or the social cost of "information overload"; the minimal cost of providing a warning even in marginal cases; and the competency of juries to apply the traditional doctrine.

INTRODUCTION

This Article comments upon the thoughtful piece by Professor Mark Geistfeld and more broadly, presents our arguments in favor of the current draft of the duty to warn doctrine presented in the Restatement (Third) of Torts: Products Liability. We contend that a risk-utility analysis is misplaced in the warning
defect context, and that other forms of economic analysis are similarly unavailing. In addition, we are critical of comments made by the Reporters in the draft Restatement to hedge in the duty to warn, and we defend the current state of the practice.

The concepts of a duty to warn and a product defect arising out of an inadequate warning are used synonymously in the draft Restatement (Third) commentary and in this Article. The draft Restatement (Third) sets forth the formulation of what constitutes a defect in the labeling of a product:

[A] product is defective because of inadequate instructions or warnings when the foreseeable risks of harm posed by the product could have been reduced or avoided by the provision of reasonable instructions or warnings by the seller or other distributor, or a predecessor in the commercial chain of distribution, and the omission of the instructions or warnings renders the product not reasonably safe.4

This well-accepted definition of the duty5 appears in most texts and decisions.6 Unlike some of the more controversial “restatements” of products liability law elsewhere in the draft Restatement, this statement has escaped meaningful debate. Controversy arises, however, from the re-analysis of the duty to warn performed by Professor Geistfeld,7 as well as others,8

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4. Tentative Draft No. 2, supra note 2, § 2(c).
5. The draft Restatement (Third) properly makes no distinction between warnings, directions, and instructions. Those terms often are summarized in this Article by the term “warning” or “labeling.”
6. The proposed Restatement (Third) takes the fundamental course of attempting to eliminate distinctions between strict liability and negligence, and instead would create liability if the product is defective. See Tentative Draft No. 2, supra note 2, § 2; see also id. § 1 cmt. a, at 4 (“Rather than perpetuating confusion spawned by existing doctrinal categories, §§ 1 and 2 define the liability for each form of defect in terms directly addressing the various kinds of defects.”). One type of defect is “inadequate instructions or warnings.” See id. § 1(b). Undoubtedly, however, a negligence standard is employed in defining the warning defect, see supra text accompanying note 4, in that three modifiers are used to invoke the negligence standard: the risk must be “foreseeable”; the warnings to be given need be merely “reasonable”; and the product need be only “reasonably” safe. See id. § 2(c).
7. See generally Geistfeld, supra note 1.
8. See Theodore S. Jankowski, Focusing on Quality and Risk: The Central Role of Reasonable Alternatives in Evaluating Design and Warning Decisions, 36 S. Tex. L. REV. 283, 326–39 (1995) (arguing that to supply balance to risk-utility analysis in defect-in-warnings cases judges must focus on reasonableness of warnings and the functionality of the warning’s “risk communication” instead of on completeness of warnings and their effect on the utility of the “whole product”); see also Symposium,
including a law review article by the two Reporters on the project, Professors James Henderson and Aaron Twerski. Further, the official comments and reporters' notes, as compared to the black letter of the law, introduce another layer of controversy.

I. ECONOMIC ANALYSIS, INCLUDING RISK-BENEFIT ANALYSIS, IS NOT PERTINENT TO ANALYSIS OF THE DUTY TO WARN

The new Restatement proposes to place the use of a risk-utility analysis at the heart of one of the main bases for liability: the product design. Once plaintiffs assert that a product was defective by virtue of design, they are then obliged to present an evaluation of the risks and costs associated with the product as contrasted with its utility. Indeed, a highly controversial requirement built into the black letter law of design defect requires that plaintiffs demonstrate a "reasonable alternative design," one that would have been of similar utility, of no greater cost and yet of greater safety.

Professor Geistfeld and others suggest that the risk-utility test is incorporated likewise into the parallel section of the draft Restatement (Third) on a warning defect. Not only is the

*Proposed Restatement (Third) of Torts: Products Liability, 21 WM. MITCHELL L. REV. 361, 389–401, 415–17 (1995) (presenting articles that compare duty to warn in Restatement (Third) with the duty to warn in Minnesota, and that criticize the Restatement (Third) for its exclusive focus on the conduct of manufacturers and for the absence of a requirement that manufacturers remain mindful of consumer expectations); William H. Hardie, *Use of Product Warning Labels as a Reminder*, 24 Prod. Safety & Liab. Rep. (BNA) 739, 748 (Aug. 9, 1996) (noting that the “law does not impose on manufacturers any duty to compel behavioral compliance with warnings”).


10. *See Tentative Draft No. 2, supra* note 2, § 2(b); *see also id.* § 2 cmt. a, at 14 (noting that when analyzing defects based on inadequate warnings “some sort of independent assessment of relevant advantages and disadvantages . . . is necessary”).

11. *See id.* § 2(b).

12. *See id.* § 2 cmt. e (suggesting that a broad range of factors may “be considered in determining whether an alternative design is reasonable” including overall safety, effects of the alternative design on production costs, product longevity, maintenance and repair, aesthetics and marketability).

black letter statement devoid of such language, neither the comments nor the reporters’ notes indicates that a judge or jury should consider such an analysis in determining whether a warning was adequate. One therefore could attempt to rest a case by showing the absence of any such language, especially because every nuance of the proposed Restatement’s language has been reviewed extensively.

A. The Role of Economic Analysis

It is hardly surprising that someone who analyzes legal doctrines from an economist’s standpoint would examine the rule of law in the warning area in economic terms. In general, Professor Geistfeld would have the trier of fact consider the costs involved in creating a label of the type a plaintiff contended was adequate. His definition of costs, however, includes the social costs to the consumer of having to read a longer label, rather than just the economic price of printing that label. He would attempt to analogize this cost to the expense a supplier would incur in adding to a product certain features (such as a safety guard) that would make the product unreasonably expensive from a purchaser’s perspective.

Courts, in their practical approach to dispute resolution, have rejected the use of a risk-utility test in the warning defect area, and in particular have refused to regard the time of the consumer’s increased label reading as a “cost” in the calculus of liability. For example, in Ross Laboratories v.

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14. See Tentative Draft No. 2, supra note 2, § 2(c).
15. See id. § 2(c) cmt. h & reporters’ note.
16. The drafting of the proposed Restatement (Third) began in 1992 with the American Law Institute’s (the ALI) appointment of the 15 Reporters and Advisors. The senior author is one of the 15 Advisors. Numerous meetings have occurred over the years with the Advisors, the Members’ Consultative Group, and the Council of the ALI.
17. See Geistfeld, supra note 1, at 327.
18. See id. at 322–23.
19. Cf. Davis v. Wyeth Lab., Inc., 399 F.2d 121, 129–30 (9th Cir. 1968) (stating that manufacturer of polio vaccine had a duty to warn of one in a million chance of contracting the disease after vaccination); Butler v. L. Sonneborn Sons, Inc., 296 F.2d 623, 626 (2d Cir. 1961) (noting that the burden of warning about improper product use was small when balanced with the danger the warning could prevent); Ross Lab. v. Thies, 725 P.2d 1076, 1079 (Alaska 1986) (finding that the cost of giving an adequate warning is so minimal that “balance must always be struck in favor of the obligation to warn” where ordinary user will not recognize a danger from the product); Moran v. Faberge, Inc., 332 A.2d 11, 15 (Md. 1975) (finding the cost of giving a warning about
Thies, an infant suffered serious injuries from ingestion of an undiluted liquid glucose product. The court refused to engage in a cost-benefit analysis to determine whether the warning was adequate because "[t]he cost of giving an adequate warning is usually so minimal . . . that the balance must always be struck in favor of the obligation to warn . . . ."

At best, courts give lip service to the use of a risk-utility test in warning defect cases, but make the use of the test meaningless in practice by limiting the cost concept to the suppliers' costs of providing a warning, always a negligible factor.

Academics are split on the advisability of resort to economic analysis in duty-to-warn cases. Professor Howard Latin has argued quite convincingly that the risk-utility test has no role in warning cases, in part because the courts have no basis by which to measure the "utility" part of the equation. He also comments that application of this sort of balancing test, as useful as it may be in design cases, would not achieve any greater consistency in liability determination than the present mode of jury presentation.

Those who are particularly critical of the present status of the law in the warning area, with Professors Henderson and Twerski chief among them, perceive a general, fundamental error in allowing suits to proceed on a defect-in-warning theory. The reasons as variously expressed are that doing so invites lawlessness on the part of the jury, and courts have no

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hard data by which to measure whether, as a matter of law, a warning should have been given or whether a jury verdict should be set aside as against the weight of the evidence.

The rather strident criticisms of the Restatement (Third) Reporters failed to become a part of the black letter of the draft. The most logical explanation for that failure is that the Reporters recognized that their views did not reflect the mainstream analysis of the warning defect. Nonetheless their views have infiltrated the comments and reporters' notes. This is notable in their discussion of the law in the areas of "information overload," duty to warn of "open and obvious" dangers; and the "allergy" situation. Regarding these three branches of duties in the warning area, the Reporters' comments in these areas subversively attempt to undermine the general and well-accepted rule.

B. Warnings for Purchase vs. Warnings for Use

The Restatement draft, Professor Geistfeld, and others draw a distinction between warnings or other information used for decisionmaking by a prospective purchaser and for methods of safe use of the product. In the former situation, the user reads the label before purchase (e.g., in the drugstore) and supposedly decides whether to use the product and knowingly assume its unavoidable risks. This concept is sometimes called "informed consent." In the latter situation, warnings and

27. See id. at 265–71 (criticizing the failure-to-warn doctrine as theoretically flawed and practically unworkable).
28. Id. at 297–99, 297 n.139, 305–06.
29. See discussion infra Part II.
30. See Tentative Draft No. 2, supra note 2, § 2 cmt. h ("Warnings alert users to the existence and nature of product risks so that they can prevent harm either by appropriate conduct during use or consumption or by choosing not to use or consume.").
31. See Geistfeld, supra note 1, at 311–12 n.11 (arguing that the de facto presumption that an adequate warning would have prevented the injury is necessary to give sellers sufficient incentive to disclose information pertaining to unavoidable risks, but is not necessary to supply the incentive to disclose information pertaining to product use).
33. See Fischer, supra note 32, at 271–72.
directions tell the purchaser how to use the product safely and avoid the danger. This function is sometimes referred to as the warning's "risk reduction."34

Professor Geistfeld concentrates almost exclusively on the informed consent aspect of a warning.35 Our first response to this concentration is that litigation rarely rests on an informed-consent theory. Most warning cases that the senior author has handled involved the adequacy of the labeling as it relates to proper use of the product. Product users are often not purchasers (consider the operator of a machine in a factory or a pedestrian hit by a defective vehicle). Finally, even purchasers decide whether to buy a product for reasons other than warnings about unavoidable side effects associated with the product, and instead call a lawyer only when they feel that their injury resulted from not being warned about the risks associated with use of the product.

Why a proponent of risk-utility analysis would choose to posit for examination the purchase-informed consent paradigm is understandable. It is here, if anywhere, that one could start to think about a risk versus benefit analysis: The buyer considers the condition he has for which he is purchasing the product or considers what are the side effects from using it. When one claims that directions for use were inadequate, however, nothing in the actual conduct of consumers lends itself to analysis of costs and benefits; they merely desire to proceed safely.

II. UNDERMINING THE BLACK LETTER DUTY TO WARN BY LIMITING IT IN COMMENTS

One reading of the text of the proposed Restatement (Third) finds a firm commitment to the imposition of a duty to warn and to submitting questions of adequacy to the jury. The comments and reporters' notes, however, tend to undermine the proposition by suggesting to courts ways to withhold certain cases from the jury. This section considers three of these suggested media.

34. See Twerski & Cohen, supra note 32, at 622.
35. See Geistfeld, supra note 1, at 345-48.
A. "Information Overload"

Academics, cognitive scientists, and economists have advanced the concept that too many warnings can be undesirable. The theory is that if users see a mass of material on a label they will decide to read nothing, or they will read a portion of the label, but somehow will miss the important part that relates to their use. In practice, defendants use the "overload" concept as a defense or excuse, when a warning about a particular hazard was omitted but later proves germane to the safety of the product. To have included a warning regarding the pertinent risk, defendants allege, would have resulted in undesirable information overload.

Although the comments of the draft Restatement contain nothing about the risk of requiring too numerous warnings, the reporters’ notes provide some case authority for the proposition. Not all professors with economic or cognitive training, however, embrace the overload concept. A team of law professors and economists have produced an examination in which they undermine the concept of information overload. In their view, rather than inducing consumer paralysis, a large quantity of information assists the user in researching the data needed to make a decision about the safe use of a product.

Thus, because consumers select a few attributes of a product to

36. See Geistfeld, supra note 1, at 310 (noting that "overenforcement of the liability standard provides an incentive to sellers to overwarn about product risks, which undermines the effectiveness of product warnings"); Naresh K. Malhotra, Reflections on the Information Overload Paradigm in Consumer Decisionmaking, 10 J. CONSUMER RES. 436, 438 (1984) ("When presented with ‘too much’ information, consumers may become confused, so that they are unable to effectively and efficiently process the information . . . ."); Debra L. Scammon, "Information Load" and Consumers, 4 J. CONSUMER RES. 148, 148 (1977) ("[T]he utilization of product information by consumers in their purchase decisions depends both on the availability of information and the processability (simplicity/complexity) and usefulness of the information to the consumer.").

37. The California Supreme Court recently rejected a defense of information overload in a pharmaceutical case. See Carlin v. Superior Ct., 920 P.2d 1347, 1351-52 (Cal. 1996) (rejecting a manufacturer’s claim that requiring “warning of dangers that were known to the scientific community at the time it manufactured or distributed the product” would lead to “overlabeling”).

38. See Tentative Draft No. 2, supra note 2, § 2 reporters’ note cmt. h.


40. See id. at 286–87.
serve as a basis of comparison with other products,\textsuperscript{41} they conclude that detailed disclosure actually can reduce costs to consumers of acquiring and processing information.\textsuperscript{42}

In many ways, the debate about overload centers too much on theory and not enough on reality. Readers of this Article, all of whom are label readers, surely have noted that information can be presented in an attention-getting format by listing information hierarchically. The prominence of location, type size, or color can emphasize serious risks. In our view, information overload should not deter anyone from providing complete and accurate warnings on labels.

B. "Open and Obvious Danger"

Commentary in the proposed \textit{Restatement} gives credence to the concept that products need not contain warnings about "obvious and generally known" risks.\textsuperscript{43} The comment, at least, is rather tepid compared to the Reporters' article on warning, which invites the judiciary to grant summary judgment in such cases.\textsuperscript{44} Indeed, the comment in the draft \textit{Restatement} would give the issue to the trier of fact where "reasonable minds may differ as to whether the risk was obvious or generally known."\textsuperscript{45} In practice, however, judges and juries have difficulty agreeing on what is an obvious risk simply because the meaning of the word "obvious" differs with each person's perspective. Thus, many writers have been critical of the "open and obvious" danger rule excusing duty.\textsuperscript{46}

The typical case that the senior author has handled involves a risk that seems obvious to most highly intelligent people, yet

\begin{footnotes}
\footnotetext{41}{See \textit{id.} at 281–82.}
\footnotetext{42}{See \textit{id.} at 294.}
\footnotetext{43}{Tentative Draft No. 2, \textit{supra} note 2, § 2 cmt. i; \textit{id.} Reporters' note cmt. i.}
\footnotetext{44}{See Henderson & Twerski, \textit{supra} note 9, at 316–17 (arguing that too many cases involving arguably obvious dangers make their way to juries).}
\footnotetext{45}{Tentative Draft No. 2, \textit{supra} note 2, § 2 cmt. i.}
\end{footnotes}
obscure to others. In the real world, all types of people use dangerous machinery and chemicals, both in the course of their employment and for enjoyment. Because the intelligence of users of hazardous machines can vary so widely, an “obvious” danger cannot be defined accurately. Thus, the product supplier should be required to issue warnings to all types of persons, even if the risks would be apparent to some. After all, the warnings serve as reminders to all users.47

C. The “Allergy Rule”

In a comment, the drafters of the Restatement (Third) give credence to yet another instance where a warning might not be due: where only a small part of the population is potentially at risk.48 The draft Restatement (Third), however, leaves the issue fluid. It states that a manufacturer will have a duty to warn when a “substantial” number of persons might react adversely to some drug or chemical and it acknowledges that what is substantial “is not precisely quantifiable.”49

Once again, one might ask what the drawback would be to warning a very small but easily identifiable portion of the population about serious risks that pertain to their use of a product. For example, very few people are phenylketonurics, yet they need to know if a product contains phenylalanine because its consumption could be brain damaging. One wonders how many persons who are not phenylketonurics resent being exposed to this labeling or how many complain of the Geistfeld concept of an extra cost involved in having to read it. Indeed, even if people are not at risk, by being educated they can share the information with others who might be at risk.

Professor Geistfeld criticizes the failure of the drafters to provide any special rules, whether by black letter or commentary, for proof of causation in warning cases.50 Instead, the draft Restatement (Third) states that the general laws of causation,

49. Id. § 2 cmt. j.
50. See Geistfeld, supra note 1, at 310–12 & nn.10–11.
as set forth elsewhere in the *Restatement (Second) of Torts*, are to be applied. This approach, we believe, is correct as to the warning defect. Many states have created presumptions or similar evidentiary concepts for the situation where no warning or an inadequate warning is given, and the plaintiff or decedent wants to assert that, had an adequate warning been given, it would have been heeded. The *Restatement (Third)* does not discuss this point of the law of evidence, much less undermine or replace it.

III. IS THERE A GENUINE BASIS FOR ALARM ABOUT LETTING JURIES DECIDE WARNING DEFECT CASES?

If the traditional concept of duty to warn in products cases is so wrong, why has the third ALI *Restatement* of that duty continued to reaffirm traditional law? To answer this requires, first, an analysis of the reasons given by critics. Their attacks proceed upon the belief that the current rule encourages "lawless" practice, in that a court has almost no guidelines for determining which cases should go to the jury and which should not. Further, they claim that there is no restraint upon plaintiffs' telling the story their way about what they read and knew. Additionally, they claim that any requirement that proximate cause be shown has all but been abandoned.

When one delves more deeply into these criticisms of the operation of warning duty law, one senses a more fundamental distrust of the judge and jury system in this country, sometimes expressed openly, sometimes covertly. Drawing a comparison

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53. *See*, e.g., General Motors Corp. v. Saenz, 873 S.W.2d 353, 358–59 (Tex. 1993); Menard v. Newhall, 373 A.2d 505, 506 (Vt. 1977). *See generally* Fischer, *supra* note 32, at 274–75, 278 ("A very common approach [to a plaintiff's problem of proving causation] is to create a rebuttable presumption that if an adequate warning had been given it would have been read and heeded.").
54. *See* Henderson & Twerski, *supra* note 9, at 271 (commenting that the problems associated with the duty to warn "may defy solution").
55. *See id.* at 289–91.
56. *See id.* at 305–06.
57. *See id.* at 306.
58. *See, e.g.*, Steven I. Friedland, *The Competency and Responsibility of Jurors in Deciding Cases*, 85 Nw. U. L. Rev. 190, 190 (1990) ("In recent years, jurors increasingly have been criticized as being ill-equipped to adequately decide the issues in cases before
to design liability, the critics find no "hard evidence," no scientific proof, no economic certainty, by which they (as surrogates for the judicial system) can measure whether or not issues are being properly adjudicated.\footnote{59}

In defense of the current practice, the question presented becomes where the authority comes from to use the definition of design defect as the standard by which labeling duties are to be measured. Perhaps in the design defect context, the proposed \textit{Restatement (Third)} has overstepped itself somewhat by intruding into the trier of fact's sphere by requiring proof of the "reasonable alternative design."\footnote{60} Certainly the current system of determining whether a manufacturer was careless in not providing an adequate warning is no more "lawless" than the application of the "reasonable person" standard to other forms of human conduct, such as driving motor vehicles and maintaining sidewalks.\footnote{61}

In practice, numerous restraints exist on the operation of law in cases involving defective labeling, including the limits placed by the "open and obvious" doctrine and the other concepts evaluated above—even if we feel that too much emphasis on those concepts may remove cases where reasonable persons could differ from jury consideration. Beyond that, judges' instructions provide a restraint on jury behavior.\footnote{62}

Another restraint is embodied in the requirements relating to proof of causation, factual and proximate, where a plaintiff's failure to carry the burden of proof often leads to loss at trial or to reversal of a favorable verdict on appeal. In analyzing this area, one must consider the factual situations that present themselves in actual litigation. Two crucial variables are the quality of the warning and whether the plaintiff read it. These produce the following situations:

\begin{quote}

them.
\end{quote}

\footnote{59. See Henderson & Twerski, \textit{supra} note 9, at 297, 305.}
\footnote{60. See Tentative Draft No. 2, \textit{supra} note 2, § 2(b); see also Marshall S. Shapo, \textit{In Search of the Law of Products Liability: The ALI Restatement Project}, 48 VAND. L. REV. 631, 676 (1995) ("It is judges, and sometimes juries, who should make the decision about the risk-utility comparison—as well as the reasonable consumer expectations—associated with a particular product. A 'Restatement' should not limit that decision to cases in which a claimant can show a reasonable alternative design.").}
\footnote{62. See Henderson & Twerski, \textit{supra} note 9, at 290.}
a. No warning made
   i. plaintiff read label
   ii. plaintiff did not read label

b. Some warning made which plaintiff read, but which may not be adequate

c. Adequate warning made, but plaintiff did not read it

Not all of the above factual situations will be submitted to a jury for resolution, notwithstanding the dire statements of various writers. For example, if a plaintiff did not read an adequate warning, the case will probably be dismissed. If a necessary warning were omitted, but the plaintiff did not read the label anyway, the plaintiff will have difficulty creating a proximate link between the missing warning and the injury sustained.  

Virtually every case on labeling that the senior author has handled has been met with a defense based on causation. The defendant invariably argues that any fault in the labeling did not cause the plaintiff's injury. In a recent experience where an over-the-counter cold remedy contained no warning about consumption with another drug, the defendant presented a labeling expert with a Ph.D. in communications, who opined that the plaintiff would not have heeded any warning given because he was an alcoholic and a lapsed Mormon, and that in another context he had failed to heed a doctor's warnings about mixing drugs.

CONCLUSION

The failure to warn doctrine, like all others, needs a straightforward legal standard, but the risk-utility test does not provide such a standard. Even though the risk-utility test has evolved as the leading judicial method to evaluate complex product design issues, it would not function as an effective tool in the

63. See, e.g., Bloxom v. Bloxom, 512 So. 2d 839, 850–51 (La. 1987) (precluding recovery because, even though warning in driver's manual was inadequate, the owner never read the manual).
warning area because it provides no guidelines for manufacturers on how to increase the quality of warnings. Nor would the tasks of judges and juries be assisted by the use of a risk-utility test.