Toward a Proper Role for Hazard Warnings in Products Liability Cases

W. Kip Viscusi

The emergence over the past two decades of design defect doctrine with respect to hazard warnings has greatly expanded to role of products liability. If a potentially risky product does not include an adequate warning, the firm can be found liable for the accident without a manufacturing defect or defective physical product attributes. In effect, the product design concept has expanded to encompass the product's hazard warnings.

This change is not innocuous. The addition of hazard warnings as a potentially defective product attribute is not comparable to including, for example, machine guards as a potentially defective product component. Consideration of other physical dimensions of the product that directly relate to safety performance do not change the general character of the liability test. Inclusion of hazard warnings, however, alters the criteria for assessing the presence of a defect. The major issue is no longer the physical properties of the product but rather how the product will interact with the product user. In particular, does the product include sufficient risk information so that the user can be informed of the risk of its use and the necessary precautions?

Resolving this issue is not a matter for engineering studies, as it would be in the case of other alleged defects. Rather, one must turn to different classes of evidence regarding how individuals process information and make their subsequent decisions. This shifting character of the evidence has also been accompanied by a decrease in the reliability of the evidence used to assess liability since warnings cases are seldom based on objective, scientific criteria for assessing a product defect. The net effect is to augment the already considerable degree of uncertainty that firms face with respect to their prospective liability. The purpose of this article is to outline scientific criteria for warnings assessment and to indicate the proper role for warnings in determining enterprise liability.

The increased attention to hazard warnings is not an idiosyncratic property of tort liability. There has been an emerging "right-to-know" movement at several governmental levels and society at large.

There have, of course, been many long-standing warnings programs. Chief among these are the FDA's risk labeling efforts for pharmaceutical

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products and EPA’s pesticide labeling efforts. Beginning in the 1960s, the
government’s emphasis on the role of hazard warnings increased. Congress
mandated hazard warnings for cigarettes in 1965 and subsequently modified
them in 1969 and 1984.\(^1\) Similarly, Congress imposed hazard warnings on
products containing saccharin in 1977.\(^2\)

The 1980’s witnessed a proliferation of warnings efforts throughout the
Federal government. The Occupational Safety and Health Administration
initiated required hazard communication provisions for all manufacturing
workers exposed to hazardous chemicals. The Environmental Protection
Agency initiated similar right-to-know provisions with respect to Superfund.
Even some individual states introduced risk communication efforts. The most
extensive of these measures has been California’s Proposition 65, which re-
quires that California residents be informed of all carcinogenic exposures
from food products, their jobs, or the general environment.\(^3\)

The increased reliance on warnings emerged in part from the greater
recognition of the limits of technology-oriented regulations. Accidents gen-
erally are the result of the interaction of the behavior of the user and the
technological characteristics of the product within the context in which the
product was being used. Although some studies of job-related accidents at-
tribute the overwhelming majority of such accidents to the failure of workers
to take appropriate precautions,\(^4\) precise assignments of responsibility are in-
feasible. What is clear is that fostering efficient risk management requires
that we address all contributors to product risks, not simply the physical
attributes of the product alone.

An impetus for warnings programs also emerges from the difference in
risk information possessed by the producer as compared with the consumer.
The producer is responsible for the product design and has a larger base of
direct research as well as product accident reports to draw upon in forming
such assessments. Companies should not, however be expected to provide
warnings with respect to information that we cannot reasonably expect them
to have. Asbestos companies should not, for example, be found strictly liable
for having failed to warn about the unknown and unavoidable product risks.\(^5\)

The rationale for providing this information to product users is to foster
improved decisions. Unfortunately, the popular designation of such efforts as
“right-to-know” policies is to some extent a misnomer. The main concern
is not with individual rights in circumstances in which no actions will be

\(^1\) 15 USC § 1331-1431 (1982).
\(^2\) The Saccharin Study and Labeling Act (Nov. 1977).
\(^3\) Emergency Regulations, Art. 6, § 12601 (b) (4) (A), to be codified at CA Admin.
Code Tit. 22, § 12601 (b) (4) (A).
\(^4\) Viscusi (1983).
\(^5\) Alameda County Complex Asbestos Litigation, Calif Ct App 1st Dist, Nos. A037335
and A037462, 9/20/88.
affected. Rather, the justification for risk communication requirements is that it will be more efficient for people to know about the risk since they will be better able to choose their risk exposures and their risk precautions after this information has been provided.

Since the ultimate objective is to promote improved decisions, the limitations that individuals have in processing information and in making decisions involving risks must be taken into account in the design of hazard warnings programs. It is for this reason that assessments of the adequacy of a warning is more complex than simply noting whether a particular risk has been mentioned. Engineering formulas for hazard warnings are infeasible since recognition of the cognitive factors influencing the processing of risk information is central to warnings design. If individuals were not constrained in this manner, health risk warnings could simply consist of referring individuals to an appropriate bibliography of scientific articles.

**Objectives of Hazard Warnings**

The overall objectives of hazard warning efforts should be to convey the risk level, appropriate precautions, and the relationship of these precautions to reducing risks. The ultimate intent of such efforts is to influence individual decisions, which arise in two different contexts. The first set of choices pertains to what might be labeled as threshold product decisions. In particular, will the consumer purchase the product or choose to use it in a particular circumstance? The second class of decisions concerns precautionary behavior, given the use of the product.

Consider first the threshold product choice decision. In this situation, an individual is usually engaged in a discrete decision as to whether or not to purchase or use the product. The intent of warnings for cigarettes, for example, is to apprise consumers of the potential risks of smoking so that they can make an informed choice. If our objective were to eliminate this behavior, then it would be more appropriate to ban such activity. Society has banned some products, including heroin and crack. In addition, it restricts the use of products in particular instances, as in the case of prescription drug requirements and age requirements for the purchase of alcoholic beverages. In a democratic society, our warnings objective should be informed choice except in extreme cases where bans are warranted.

Most studies of hazard warnings equate reductions in the risky consumption activity as signs of warnings efficacy. Observers note with approval situations in which consumption of a product diminishes after a warning has

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6. See, for example, the report prepared for the Office of Policy Analysis National Institute on Alcohol Abuse and Alcoholism by Macro Systems, Inc. (1987). This influential report, which formed the basis for the Congressional imposition of mandatory labeling of alcoholic beverages, mistakenly equates labeling impact with efficacy.
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been given, such as the drop in cigarette smoking and the decline in the purchase of diet soft drinks containing saccharin following these Congressionally mandated warnings. Such consumption effects indicate a negative shift in attitudes toward a product, but they do not tell us whether the warning has fallen short of the expected impact or whether the warning has been unduly alarmist. If declines in product use are a signal of success, then a product ban would have produced the greatest gains. Presumably, society has more limited objectives that should be recognized.

A major factor conditioning how individuals respond to communication of information about product risk levels pertains to the cognitive factors governing risk perception. In particular, individuals tend to overestimate risks that are called to their attention and low probability events. Since product risks tend to be small, informing individuals about these risks may make people believe that the risks are larger than they actually are.

The dangers of overly alarmist warnings are illustrated in the case of the hazard warning language adopted for food cancer warning under California Proposition 65, which was an initiative intended to promote broad consumer awareness of cancer product risks. Although the exact implementation of the warning is continuing to evolve, the wording of the warning mandated by the regulation is the following:

"WARNING: This product contains a chemical known to the state of California to cause cancer."

Products to be covered by this warning include all consumer products that pose a lifetime risk of cancer of one chance in 100,000, or a risk from annual consumption of the product of one in 7,000,000. This probability is smaller than the chance of being struck by lightning, which is too small a risk for most people to think about precisely.

The wording of the warning does not, however, convey a minimal risk. Rather, individual assessments of the impact of this warning as compared with risks posed by other products indicates that the warning conveys a very powerful message. Fifty-six percent of all individuals regard the saccharin warning ("Use of this product may be hazardous to your health. This product contains a chemical that has been determined to cause cancer in laboratory animals.") as indicating a product with less risk than the Proposition 65

8. Individuals, for example, greatly over-estimate the risks of death from highly publicized events such as earthquakes and tornadoes, but consistently under-assess much more consequential risks such as the chance of dying from heart disease or stroke. See Fischhoff, et al. (1981).
9. CAL Admin. Code Tit. 22, § 12601 (b) (4) (A).
warning.  

10. For supporting discussion with respect to these and other impacts of Proposition 65 discussed in the paragraphs above, see Viscusi (1988).


of competing risks of labeling is to pretest the warning language and structure of the information provided to ensure that we are accomplishing our intended objective.¹³

Warnings intended to promote precautionary behavior raise a somewhat different class of issues. In this case the objective is not simply to apprise individuals of the risks they face, but also to indicate how they can reduce these risks through their actions. Consumers generally know how to handle obvious product risks, such as those posed by sharp knives. The emphasis of warnings should be on providing information with respect to precautions for which the producer has some superior knowledge.

It will seldom be the case that the yardstick for judging precautionary labeling will be the extent to which all individuals take a particular kind of precaution. Precautions are often onerous. Individuals could, for example, rationally choose not to wear particular kinds of protective equipment if they felt it was too burdensome to do so.

In situations in which we wish to require precautionary behavior, as opposed to only providing information and exhortation, the more appropriate solution is a more mandatory form of regulation. Society, for example, requires that motorcyclists wear helmets since motorcyclists who are injured inflict costs on others who must pay for accident-related damages. Unfortunately, when behavior is decentralized and cannot be monitored, strongly worded precautions with voluntary decisions may be the only mechanism available to promote risk-averting activities. We can monitor motorcycle helmet use much more easily than whether consumers dilute pesticides to the proper concentration.

The nature in which hazard warnings influence precautions is illustrated by the effect of different labels for a drain opener (summarized in Table 1)—a frequent target of hazard warnings litigation. Three different warnings were considered by a group of consumers assessing three hypothetical products with professionally drawn labels. The first label is patterned after a composite of the Drano and Red Devil Lye labels. A second product with a redesigned label not similar to any products now marketed was also examined. This Test label incorporated a clear labeling format, but carried much less extensive risk information than the Drano/Red Devil Lye label. Finally, a third group

¹³ Although such studies have been undertaken for Proposition 65 warnings and for a variety of consumer products such as household chemicals and pesticides, few regulatory agencies or firms have done so. In the face of substantial uncertainties regarding the nature of individual response to warnings, there should be an effort to acquire information as to the impact these policies will have before we launch efforts that will have fundamental effects on the risk taking behavior. Put somewhat differently, there should be an effort to devote the same kind of pretesting and prior assessment of the impact of hazard warnings as is devoted to the test marketing with respect to other attributes of products.
of consumers considered the Drano/Red Devil Lye label but with the warning information purged from the label. The two major precautions for the products examined in the survey were that consumers should wear rubber gloves to avoid hand burns, and they should store the product in a childproof location to decrease the risk of child poisoning.

Several results are noteworthy. First, even in the absence of any warning information, many consumers will take precautions such as these. For labels without any warning information, the majority of all respondents would wear rubber gloves, and the majority of all individuals with children would store the product in a childproof location. Individuals may be generally aware of the types of risks that arise with respect to a class of products, perhaps in part due to past warnings efforts. The second result of interest is that in none of the cases did the warning result in universal precaution taking. The maximum incremental effect of labels was to boost the fraction of individuals with children under five who would store the product in a childproof location, where this fraction rose from 70 percent if no warning were given to 90 percent in the presence of the Drano/Red Devil Lye warning.

Partial impacts on precautions such as these may arise for a variety of reasons. First, not all individuals will read, process, and take actions in response to hazard warnings. Second, and perhaps more fundamentally, it will not always be rational for them to do so. The consumers participating in this study indicated that they would be willing to pay an extra 17 cents per bottle to avoid having to wear rubber gloves while using the product. Individuals who found wearing of rubber gloves more costly than the expected injury costs imposed by a hand burn from toilet bowl cleaner might rationally choose to forego the recommended precaution.

The final noteworthy feature of the results in Table 1 is that the degree to
which people take precautions will be influenced by the particular risks that they face. Households with children are more likely to store drain opener in a childproof location than those who do not. The hazard warning label also has a greater impact on these childproofing decisions even though the base level of childproofing in the absence of the warning was higher when the household included children under the age of five. This evidence suggests that individuals can use warning label information to make sensible risk balancing decisions.

Criteria for Warnings Assessment

There are two classes of criteria for assessing whether warnings fulfill their objectives of providing appropriate information with respect to product risks and precautions. In each case, these criteria will be governed by the fact that we are dealing with the interaction of warnings with the decision making capabilities of the warnings recipient.

Principle 1: Warnings should be judged using a hazard communication system perspective.

The first principle for judging warnings is that one should assess these warnings from the standpoint of the entire hazard communication system rather than from the myopic perspective of a particular risk posed by a single product. This hazard communication system perspective arises at two levels. First, for all the risks posed by the product and the different ways in which the risk is communicated, is it desirable to incorporate a warning for the hazard involved in a particular case? Second, for the entire class of risks faced by the individual, would adopting a warning strategy such as this lead to a sensible warnings policy?

The typical warnings case on behalf of plaintiffs frequently takes full advantage of the wisdom conferred by hindsight. The plaintiff was injured by a particular risk posed by the product, and if only there had been a bold hazard warning with respect to that risk the injury could have been averted. What these experts fail to recognize is that if a warning had included information about not only that risk but about all other comparable risks posed by the product, then it might have been ineffective.

A major difficulty in providing extensive information is that of information overload. Detailed examination of the information that individuals retain from hazard warnings indicates that even with very detailed and well designed warning labels, individuals can seldom recall more than six pieces of information from a label.14 Much of this information recalled from the

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label pertains to guidance with respect to aspects of the product other than precautions and risk levels such as product uses. As we successively provide more information, individuals eventually reach a saturation point.

There is a fundamental tradeoff in terms of the information that is retained by consumer. Pesticide warnings that include much greater amounts of risk information can produce more recall of the risk information, but there is also a tendency for consumers to forget or not to process at all the information with regard to appropriate product use. Since the formulation of commercially sold pesticides is such that the major risks of pesticide products are from misuse (using inappropriate concentration of pesticides) rather than inadequate precautions during proper use, excessive risk information may actually increase the overall risk posed by the product.

With excessive amounts of information pertaining to product risks, there is a tendency for consumers to be cognizant of the risks that are present but to have a more muddled sense of the particular precautions that should be undertaken to reduce the risks. In short, not only is there a tradeoff in terms of the kinds of information that individuals retain, but there is also a distortion in the message that is received if excessive information is provided.

This result should serve as a precautionary warning for the courts, which through their decentralized treatment of case-specific risks generate incentives for a proliferation of warnings. In some cases it may not be desirable to include warnings with respect to particular risks if doing so would detract from the more fundamental risks posed by the product. One should assess the impact not only of the case-specific warning but also the efficacy of the entire hazard communication system if it were designed along similar principles.

In recent years, for example, there have been a number of lawsuits against manufacturers of lift trucks that have tipped over during use. These tipover incidents generally arise when the lift truck is driven very fast and the driver makes a sharp turn. Although plaintiffs’ experts have testified in such cases that there was a need for a very prominent hazard warning on the lift truck concerning this risk, simplistic assessments such as these ignore the demands that are placed on the hazard communication system. Lift trucks pose the entire range of hazards associated with motor vehicles, as well as the additional risks arising when carrying cargo. There are also other risks associated with the specific features of this vehicle. The training manual for this product identifies approximately three dozen potential sources of fatal injuries. Plastering warning signs for each of these hazards on the lift truck may mute some of the firm’s potential liability, but it will not improve the quality of the hazard communication system.

The multiplicity of risks does not mean that we should take no action at all when we wish to communicate more than a handful of pieces of information. Rather, in such situations we should explore other informational
mechanisms. In the case of lift trucks, the main mechanism will be the training program given to operators and the training manual accompanying the lift truck. Other information that can be provided in this context includes training films.

Similar concerns arise in other contexts as well. When evaluating pharmaceutical warnings, for example, the product labeling is only one concern. Information disseminated in medical journals, through detail men, in professional seminars, and in the general media also should be considered. Courts should shift their focus from warnings and labeling to broader assessments of the entire hazard communication system.

Courts do not always take the hazard communication system perspective. Instead, the emphasis is on the product. One such case involved an industrial toilet bowl cleaner company, which was found liable for skin burn injuries. The product warning indicated the risks of chemical burns from skin contact and the need to rinse immediately if skin contact occurred. Moreover, the overall hazard communication system for this worker was not deficient since her supervisor had told her to wear rubber gloves, a warning that was ignored. Since the worker’s set of risk information would not have been augmented by the warning, a proper application of risk communication principles would not have indicated that the warning was defective. Nevertheless, the court ruled that the warning was inadequate because it did not include the need to wear rubber gloves.

The warnings test should not be whether the on-product labeling was adequate. Rather, it should be whether the entire hazard communication system adopted by the company was sufficient given the character of the entire class of product risks, the limitations on human information processing abilities, and the availability of other mechanisms to convey information to product users. Hazard warning judgments should be made from the context of the entire risk communication system, not simply the on-product labels.

**Principle 2: The key component for judging warnings is the extent to which they provide new information in a convincing manner.**

The second criterion for warning assessment is that the adequacy of the warnings should be judged with respect to its informational content relative to the information that consumers already possess. The primary determinant of the impact of hazard warnings for workplace hazards, for example, is not the risk level conveyed by the warning but the informational content of the warning message. What matters is whether the warning conveys new

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15. This discussion is based on the 1986 case, Uptain v. Huntington Lab, Inc., Colo Sup Ct, No. 845C136.

information in a convincing manner. Warnings that are forms of persuasion or which are intended to simply serve as reminders will generally have less impact than those that provide new knowledge.

In many instances, there is an informational gap that creates the need for better product risk communication. A widely publicized series of accidents in which there is a legitimate need to warn is that of exploding tires for which there is no warning concerning the maximum safe inflationary pressure.\textsuperscript{17} Manufacturers are much better situated than consumers to know the tire inflation requirements.

Similarly, there may be an information gap even in situations for which some risks are apparent. People who play softball or baseball are generally aware that they may be hit with a ball, but it is likely that few know that the brain damage risk of being hit in the head with a softball thrown at normal speed is greater than the risks from being hit by a baseball.\textsuperscript{18}

If the hazards are widely known or readily apparent, there is no informational role for hazard warnings. Manufacturers of fork lifts are not required to warn of the hazards of operation on uneven surfaces because the danger of operating on rough terrain are apparent to the driver.\textsuperscript{19} Similarly, bullet manufacturers do not have a duty to warn about the risk of gun accidents because the risks posed by bullets are open and obvious.\textsuperscript{20} Airplane manufacturers also needn’t warn pilots about the need to lock their seats into position before take-off because “the pilot, just as the automobile driver, would, through the exercise of common sense, innately appreciate the difficulty in reaching and stably operating the controls and foot pedals from a seat which had not been secured into position.”\textsuperscript{21}

A similar principle has arisen in a series of highly publicized cases involving the link between excessive alcohol use and birth defects. Would a pregnant woman who drinks half a fifth of Jim Beam whiskey a day alter her behavior based on a warning on the bottle concerning potential birth defects? A Federal jury concluded that Jim Beam was not negligent in failing to warn pregnant women about the risks of excessive drinking.\textsuperscript{22}

\textsuperscript{17} Marchant v Dayton Tire & Rubber Co., CA 1 Nos. 87-1487 and 87-1634. Also see Firestone Tire & Rubber Co. v Battle, Texas Ct App 1st Dist, No. 01-87-00241-CV.
\textsuperscript{18} The risk arises from the greater size and mass of softballs as well as their new polycore composition. A Michigan head injury case involving softballs based on inadequate warnings (Carol E. Reinhart v U.S. Slo-Pitch Softball Association, Steeles Sports Co., Liberty Park of America, and Michael Carzos) led to a settlement in excess of $1 million.
\textsuperscript{19} Collins v Hyster, Ill App Ct, 3rd Dist, No. 3-87-0785, 91-30188.
\textsuperscript{20} Schilling v Blount Inc., Wis Ct App Dist 1, No. 89-0085.
\textsuperscript{21} Argubright v Beech Aircraft Corp, CA 5, No. 88-2177, 3/28/89.
\textsuperscript{22} Thorp v James B. Beam Distilling Co., C87-1527-R, DC Wash, verdict rendered 5/18/89. Wholly apart from potential fetal alcohol syndrome risks, there is also the chance of malnutrition from a high alcohol component in one’s diet.
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Although the courts have sometimes recognized the role of existing information, in other instances products have been found to be defective because of inadequate warnings even though the new informational content of these warnings appears to be minimal. Somewhat surprisingly, tire manufacturers have been found liable for failing to warn purchasers that a blowout could result if a vehicle is carrying an excessive amount of weight. Similarly, a Federal appeals court ruled that Uniroyal was liable for the fatality of a professional truck driver because it had failed to provide a warning of the risks of underinflated tires. In each of these cases, the new knowledge that would have been provided by warnings appears to be insubstantial.

The tire industry is not the only group adversely affected by seemingly misguided warnings verdicts. Football helmet manufacturers have been particularly hard hit. A California court awarded a high school football player $11 million because the helmet manufacturer, Riddell Inc., did not include a warning label pertaining to the risks of ramming opposing players. Another example in which the product user was credited with little product knowledge is an Indiana case in which a jury awarded a woman $485,000 after she suffered injuries from the collapse of her improperly opened chaise lounge. The firm was held responsible since it had not included instructions explicitly indicating that an improperly opened chair could collapse.

The net effect of such cases is that whenever there is a remote possibility that some class of consumers may not be fully informed, or could successfully argue ex post that they were caught by surprise even when they were not, the firm will have an incentive to introduce a product warning. There is no penalty for overwarning, only for underwarning. The courts consequently create incentives for a proliferation of warnings that will ultimately inundate consumers with risk messages. The net effect will be excessive warnings, diluting the impact of the legitimate warnings in place.

Assessing whether there is an informational gap depends on who the target of the information is. Although the product user is usually the key group, often some other intervening economic agent is the principal recipient of the information. The widest class of such instances involves physicians, who serve as the “learned intermediary” between pharmaceutical companies and their patients. The producer’s task is to inform the physician, who is better

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23. Connelly v General Motors Corp., Ill App Ct 1st Dist 1st Div, No. 1-88-1081. The blowout occurred after a Buick Opel was given an 860 pound load.

24. The court ruled that it would be speculative for the jury to assume that the risks of underinflated tires was common knowledge. See Leonard v Uniroyal, Inc., CA 6, No. 84-5507.

25. Jaramillo v Riddell Inc., Cal Sup Ct (San Bernardino Cty). NO. OCV31309. The victim’s share of negligence was found to be only 7.5 percent.

trained to process the risk information and convey the risks to the patient for this particular situation. The learned intermediary doctrine shields pharmaceutical companies from liability for failure to warn provided that the physician is adequately informed.27

The knowledge of intervening economic agents arises in other contexts as well. The role of expertise other than the product supplier was recognized in a court decision regarding silica sand, as the original supplier of the sand was not found to be liable for failure to warn workers of the risks of silicosis since the company where the sand was being used was a “sophisticated user” and was best able to warn the workers.28 Similarly, carbide tool manufacturers are sophisticated users of cobalt and can be relied upon to warn their employers of potential bronchitis risks from cobalt dust.29

Sources of Evidence for Assessing Warnings

The hazard warning area is not only a relatively new area for litigation, but it is also a comparatively new field for academic research. In such a developing field, there is a danger of junk science. So-called warnings experts can provide misleading information to juries. There are always additional manipulations of the warnings that are possible to make the risk information seemingly more prominent. Warnings assessments should be based on scientific principles rather than conjecture of self-proclaimed warnings expertise.

There are four types of scientific evidence that can be used to evaluate warnings. The first is to assess the actual impact that the warnings have had on risk perceptions, precautions, and safety outcomes. Interview studies can address narrowly defined issues such as those pertaining to risk perceptions and precautions, and in many situations market data are available to assess the effect of warnings on the quantity of the product consumed. Warnings about Reye’s Syndrome that were disseminated in the media, through doctors, and on-product warning labels produced a substantial drop in aspirin use among young children.30 Similarly, there was a modest drop in the sale of soft drinks containing saccharin after the advent of on-product warnings for saccharin and the attendant publicity pertaining to saccharin risks.31 The


31. One such study of saccharin warnings is that of Schucker, Stokes, Stuart, and Henderson (1983).
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decline in cigarette use also is attributable to the surge of adverse publicity regarding cigarette hazards, including the succession of cigarette warning labels that have been placed on this product.32

What is noteworthy in all these instances is that while a change in risk information appears to be consequential, the particular contribution of hazard warnings cannot be isolated. The role of other forms of information that were contemporaneous with the hazard warnings impedes any effort to distinguish the effect of hazard warnings as opposed to other information that might have been received. To utilize market data successfully, one needs a more carefully controlled study in which one takes into account changes in the environment other than the warning label. This may be particularly difficult in practice when there are other contemporaneous informational or market events occurring, but if the data available are sufficiently extensive it may be possible to make such refined distinctions, as we will see below in the case of the market impacts of tetracycline warnings.

A second source of evidence that can be used to assess the efficacy of warnings is experimental studies. The drain opener results reported in Table 1 were of that form. The reliability of these experimental results depends on the degree to which one recreates an informational and product use context that is comparable to that actually faced by the product user.

A third procedure for evaluating impact of warning labels is to apply the principles that have been developed in the scientific literature. This procedure is generally the simplest to undertake since no new research is required. However, in carrying out such an evaluation it is important to rely upon scientifically established principles for label design as opposed to conjecture.

The final evaluation approach is to utilize established labeling guidelines as a reference point for assessing whether the particular warning chosen is appropriate. A number of institutions have established procedures for warnings. The American National Standards Institute, for example, has issued guidelines for the use of different human hazard signal words for mechanical hazards, including: "danger," "warning," and "caution." Similarly, the detailed warnings programs for pharmaceuticals and pesticides provide reference points regarding past warnings practices for these classes of products.

Use of these reference points is instructive insofar as it indicates the extent to which the warning has adhered to the appropriate labeling vocabulary for the type of risk. However, the degree of guidance provided by such labeling programs is often not definitive. Moreover, little of this work has been based on formal scientific studies of labeling efficacy. The efforts have generally been the outgrowth of an attempt to promote uniformity. The principles underlying such guidelines may not be sound, and the domain in which they

32. For a review of this evidence, see Ippolito, Murphy, and Sant (1979).
Table 2  Workers’ Risk-Utility Tradeoffs

<table>
<thead>
<tr>
<th></th>
<th>Chemical Label</th>
</tr>
</thead>
<tbody>
<tr>
<td></td>
<td>Chloroacetophenone</td>
</tr>
<tr>
<td>Initial risk assessment (0–1 probability scale)</td>
<td>0.10</td>
</tr>
<tr>
<td>Risk assessment after warning (0–1 probability scale)</td>
<td>0.18</td>
</tr>
<tr>
<td>Additional wage premium for risk required ($1982)</td>
<td>1,919</td>
</tr>
<tr>
<td>Implicit value of an injury (i.e., value per statistical injury)</td>
<td>23,988</td>
</tr>
<tr>
<td>Would not stay on job at any wage (fraction)</td>
<td>0.02</td>
</tr>
<tr>
<td>Intend to quit if no wage increase (fraction)</td>
<td>0.23</td>
</tr>
<tr>
<td>Would take the job again if no wage increase (fraction)</td>
<td>0.58</td>
</tr>
</tbody>
</table>

Source: Based on calculations by the author and data in Viscusi and O’Connor (1984).

can be applied may be limited. Nevertheless, warnings reference points such as this may establish some guidance with respect to how different types of warning language are used.

Warnings and the Risk-Utility Test

The risk-utility test used to assess strict products liability for design defects has several implications with respect to role of warnings. First, if hazard warnings are effective in fully communicating the risk, then any additional examination of whether a product design is defective is redundant since the market has already performed such a risk-utility test. The second implication is that when analyzing whether a warning should be imposed, one should apply the same kind of risk-utility balancing in assessing warnings as one would in analyzing other aspects of product design.

Consider first the automatic character of the risk-utility test. If the warning message is received and processed reliably, individuals making consumption decisions will incorporate the value of the risk reduction to them. This value in turn will be transmitted to the producer, thus establishing incentives for the producer to take the efficient level of care.

The data in Table 2 indicate the way in which this mechanism operates in a warning situation. Two different groups of workers in the chemical industry
received warnings for chemical products and were asked how working with a chemical bearing such a warning would alter their attitude toward their jobs. The first chemical is chloroacetophenone, which is an industrial chemical that is an irritant. Although this chemical will make you cry, it will not have irreversible health impacts of a serious nature. In contrast, the second chemical for which a professionally drawn label was given to the workers was asbestos, a rather well known carcinogen.

In each case workers were asked what their initial assessment of the risk of their job was, which is given in the first row of the table. In particular, what was the probability of a standard job accident that is equivalent to the risk of working with the chemical on the warning. The initial risk assessment before receiving the warning was 0.10 for the chloroacetophenone sample and 0.09 for the asbestos labeling group. A risk of 0.10 indicates that the riskiness of the job is comparable to an annual chance of one in ten of experiencing an on-the-job injury. After being shown the warning label for a chemical that would replace the chemicals with which the individual currently worked, the risk assessments increased to a level of 0.18 for chloroacetophenone and 0.26 for asbestos.

Labeling will generate market incentives for safety if workers demand additional wage premiums to remain on the job after being apprised of the risks. These premiums averaged $1,919 for chloroacetophenone and $2,996 for asbestos. Viewed in terms of the amount that workers required for each additional expected injury on the job, these figures translate into an implicit value for each expected injury of approximately $20,000.33 This order of magnitude for the implicit value of an on-the-job injury is comparable to the amount that workers now receive for risks. As a result, risk labeling will generate the same kind of market risk reduction incentives as are now generated through the wage mechanism. A risk-utility test is superfluous in situations where these market processes are effective.

There will be additional financial incentives for safety generated through turnover costs. In the case of asbestos, 11 percent of all workers indicated that they would not work with asbestos for any wage, and 65 percent of these workers indicated that they would quit if their wage were not increased.34

The risk-utility test is based on balancing the benefits and costs of risk.

33. In particular, for chloroacetophenone, the implicit value of an injury $23,998 = 1.919 / (.18 − .10). Similarly, for asbestos, the implicit value of injury $17,624 = 2.996 / (.26 − .09). In each case, the implicit value of an injury equals the amount required to accept the risk divided by the magnitude of the risk increase.

34. Moreover, only 11 percent of the workers exposed to asbestos indicated that they would take the job again if there were no wage increase. These workers for the most part were already in high-risk jobs so that this willingness does not represent a breakdown in market functioning.
Table 3  Components of Private Risk-Utility Analysis for Drain Opener Precautions

<table>
<thead>
<tr>
<th>Costs:</th>
<th></th>
</tr>
</thead>
<tbody>
<tr>
<td>Disutility per bottle of wearing rubber gloves</td>
<td>$ .17</td>
</tr>
<tr>
<td>Number of bottles of drain opener per year</td>
<td>1.78</td>
</tr>
<tr>
<td>Annual value of costs of wearing rubber gloves</td>
<td>$ .30</td>
</tr>
</tbody>
</table>

<table>
<thead>
<tr>
<th>Benefits:</th>
<th></th>
</tr>
</thead>
<tbody>
<tr>
<td>Annual risk of hand burn from drain opener if no precaution</td>
<td>0.000061</td>
</tr>
<tr>
<td>Hand burn health effect</td>
<td>Temporary hand burns</td>
</tr>
</tbody>
</table>

<table>
<thead>
<tr>
<th>Benefit-Cost Comparison:</th>
<th></th>
</tr>
</thead>
<tbody>
<tr>
<td>Minimal dollar value of hand burns for expected benefits to exceed costs of precaution (i.e., Value (.000061) &gt; $.30)</td>
<td>$5,200.00</td>
</tr>
</tbody>
</table>

Sound warnings efforts promote this balancing for precautionary decisions. Table 3 summarizes information relevant to consumers’ decisions to utilize rubber gloves when using the Drano/Red Devil Lye composite product that was considered in Table 1. The main cost of warnings typically will not be the cost of placing a label on the container but rather the cost of the precautions to the individual of the recommended precautions. In this case, the disutility of wearing gloves is valued at $.17 per bottle, or $.30 per year for the average product usage. Individuals who wear these rubber gloves will reduce their risk of hand burns that are severe enough to require medical treatment by an average of .000061. Whether or not it is desirable to undertake this precaution depends in large part on how valuable the injury reduction is. Above some threshold benefit level precautions are desirable, and below this cutoff they are not. The calculations in Table 3 indicate that if the value of the hand burns prevented by using rubber gloves exceeds $5,200, then it is economically desirable for them to take precautions. If the loss imposed by the hand burn is less than this amount, then it would be rational to forego the precaution.

Overall, 18 percent of the sample receiving the Drano/Red Devil Lye warning chose to forego this precaution. This behavior is not necessarily irrational given the size of the threshold benefit level before precautions are desirable. Once the information has been given, received, and processed, then there is often the leeway for individuals to rationally choose not to take
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the recommended precautions. Their personal risk-utility test with respect to
the precautions may indicate that it is not worth their while to exercise the
recommended degree of care. This element of choice and the freedom to
ignore warning instructions is sometimes a rationale for instituting warnings
efforts as opposed to more mandatory stipulations.

Regulatory Compliance

A frequently suggested products liability reform proposal is to make
evidence regarding a product’s compliance with specific regulatory require-
ments should be exculpatory. This proposal is particularly pertinent in the
case of hazard warnings that are approved by government agencies. For this
regulatory compliance test to be valid in the warnings context or in any
other situation, however, the company should have provided to the regulatory
agency on a continuing basis any available information relevant to setting the
regulatory standard. In addition, the regulation should deal explicitly with
the hazard warning and do so in a manner that will promote an efficient
level of safety. Within the context of hazard warnings, this latter require-
ment hinges primarily on the degree to which there is a specific regulatory
requirement as well as the extent to which this requirement is based on an
established and effective warnings vocabulary.

Three different regulatory contexts involving warnings arise, and the ex-
tent to which regulatory compliance should be exculpatory will vary among
them. In the first situation the agency drafts the specific warning language,
which is based on an effective warnings vocabulary. Compliance with those
warnings requirements should be exculpatory. The chief examples of such
warnings are the pharmaceutical warnings mandated by the Food and Drug
Administration. The Congressionally mandated warnings for cigarettes and
saccharin are in this category as well.

In some cases, most prominently the cigarette litigation, compliance with
the warnings requirements has been ruled exculpatory, at least from the
standpoint of warnings defects. Simultaneously there are, however, limits
to the role of warnings. In a case involving toxic shock syndrome from
tampons, the courts have ruled that compliance with Federal warnings re-
quirements pre-empt claims based on inadequate warnings but not claims
based on defective product design or construction.35 Unless one can also dem-
onstrate that the warnings are fully informative, this limitation on the role of
warnings is correct from a warnings policy standpoint.

Consider, for example, the standard pharmaceutical warning. The pri-
mary audience for this warning is the physician who will write the prescrip-

tion. This warning is included in an annual compilation of warnings known as the **Physician’s Desk Reference**, and it is also distributed with the product itself. As a result, there is access to the warnings.

In addition, the audience for the warnings is not the consumer but a learned intermediary, the physician, who will act as the patient’s agent. Because of this relationship, the content of the warning can be much more complex and scientifically detailed than would a warning for a consumer product.

Nevertheless, for any recipient group it is essential to provide the information in a clear and organized manner. For pharmaceuticals the FDA has adopted a standardized warning vocabulary. In particular, each section of the warning addresses a different class of issues. The first segment of the warning provides a general “description” of the product. The second section deals with the “clinical pharmacology,” part of which raises issues that would be familiar to physicians—all of whom take pharmacology courses in medical school. The third component of the warnings message consists of “indications and usage,” so that the particular situations in which the medicine will be effective are summarized. The “contraindications” section addresses situations in which the drug should not be administered because of particular risks. The “warnings” section is devoted to various kinds of warnings concerning the drug that arise both generally as well as in particular contexts, such as with respect to usage during pregnancy. Risks that may arise but on a less general basis are addressed in the “precautions” section of the warning. The potential for adverse reactions that may occur on a random basis is highlighted in the “adverse reactions” section. After being given all of this information regarding the product risk, the physician then obtains information regarding “dosage and administration” as well as the dosage and form in which the product is supplied (i.e., “how supplied”).

Processing of this information is facilitated not only by the prior training of the physician but also by the fact the different components of the labeling information have been standardized across products. The different component sections of the label and their content is always identical. Thus, descriptive information always precedes discussion of clinical pharmacology, and so on. Moreover, the risk warnings will always appear in the appropriate section and will not, for example, be subsumed into a clinical pharmacology section. By adopting such a standardized format the user of the information can develop expertise in processing the labeling information in a systematic manner.

A second noteworthy feature is that the degree of prominence given to various kinds of information has been standardized across different warnings. The manner in which warnings are developed for pharmaceutical products ensures such a consensus. The pharmaceutical company applies for the ap-
proval of a product, and the specific wording of the warning is drafted by a group of physicians and pharmacologists within the Food and Drug Administration. By utilizing a national group of this kind that applies standardized warnings criteria in all contexts, one can establish a degree of uniformity and a common vocabulary across warnings that ensures that the content and impact of warning will have the intended effect. Bold lettering may be used to identify different aspects of the product information, particularly those regarding the risks of tooth staining. In other cases, there may be boxed lettering used, or the warning could be shifted to the first part of the label. Underlining of the warning as well as other forms of changes in its presentation also are utilized.

In contrast, if one were to adopt a warnings strategy with the objective of minimizing one's risk of liability, the solution would be to box and put in large bold lettering all warnings pertaining to products, however ineffective this approach might be from a risk communication standpoint. The company taking such apparently ambitious measures could then argue that it had done all that it could to convey the warnings message. Such overwarning may reduce liability costs, but will not lead to a sensible warnings policy. If we box and otherwise highlight warnings related to minor health impacts, then there will be no option left in our warnings vocabulary to convey more serious classes of risks. What do we do for an encore? We will dilute the effectiveness of the warnings messages for risks that merit greater concern.

The degree to which warnings can have an impact is illustrated in Figure 1. Hazard warnings for tetracycline began in April, 1963. This warning indicated a tooth staining risk—primarily in young children. Although the consequences of tooth discoloration are only cosmetic, awards in these
cases have often been substantial—sometimes in the range of $65,000-$75,000.36 The age ranges shown in Figure 1 are for the affected group 0-8 and what might be viewed as a control population group not affected by the risk, age 9 and above. What is striking is that the usage of tetracycline declined for young children beginning in 1963 from approximately 400 mentions (which consist primarily of prescriptions and renewals of prescriptions) per 1000 population to under 100 mentions per 1000 population by 1975. Physician mentions for other age groups not susceptible to the tetracycline tooth staining risks continued to increase at a modest, but steady pace until other competitive drugs began to decrease its market share in the 1970s.

This type of market evidence provides a nice comparison of what the trajectory of tetracycline usage for young children would have been in the absence of the warning. The clearcut implication is that the hazard warning was effective in this particular market context.

Usage of tetracycline in the tooth staining-susceptible age group did not completely disappear since physicians must make risk-utility tests on behalf of their patients. If a particular drug is more effective in reducing serious risks to one’s well-being, then it may be worthwhile to accept a risk of cosmetic damage. In this situation, by comparing the market segment affected by the warning with the market segment that would not be directly affected by the warning, one can establish evidence of the warnings impact that, in effect, takes into account changes in disease patterns and drug availability that might have otherwise accounted for the shift in tetracycline usage.

A second class of warnings regulations consists of those with less clearcut implications for a firm’s potential liability. There is often explicit regulatory approval of the warnings without a firmly established warnings vocabulary. Perhaps the best example of these warnings is the EPA’s labeling requirements for pesticides. Although pesticide labels must be formally approved in advance of marketing by EPA, the structure and content of these labels varies considerably even for products within the same product class. There is no well-established warnings vocabulary as there is for pharmaceuticals. The structure, content, and the format of the warning differ considerably across products in part because the warning is often drafted to accommodate the broader marketing function of the labeling material.

The variations in the efficacy of pesticide warnings are borne out in a study of different EPA approved warnings for bleach, which is officially classified as a pesticide by EPA because of its biocidal properties.37 The

36. Miller v Upjohn Co, La Ct App 1st Cir, Nos. 83 CA 1355-1356, 465, So2d 42. The Louisiana intermediate appellate court upheld these verdicts in 1985.
37. See in particular, the comparison of Clorox and Kroger-Bright brand of bleach in Viscusi and Magat (1987).
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placement and content of the warnings message varies considerably for different nationally marketed brands. The effectiveness of these warnings differs in large part because the agency is not explicitly concerned with establishing a common and effective approach to warnings, as in the case of the FDA. Although regulatory compliance with guidelines such as those administered by EPA may be exculatory, the guidelines are not sufficiently detailed to ensure that this will always be the case. Compliance with Federal labeling requirements, such as EPA-approved labeling, currently does not generally exempt companies from tort suits, and this view is consistent with my warnings proposal.39

The third situation in which warnings requirements can arise is with respect to regulatory provisions that impose warnings but do not indicate their specific form and content. OSHA's large scale hazard communication effort for job-related chemical hazards is of this type. Manufacturing firms are required to warn their workers about hazardous chemical exposures, but there are no regulatory stipulations whatsoever regarding the form, content, structure, or other aspects of the warning. There is not even any explicit regulatory guideline that one can use to assess whether the warning is in compliance with the regulatory standard. Even in situations in which the company has been subjected to a government inspection and found to be in compliance, one cannot be confident that the warnings system is sound. This class of regulatory violations may not have even been addressed by the inspector. In addition, even if the inspector did assess the warnings, the absence of a precise standard to be used for judging warning efficacy limits any inference about the desirability of the warning.

The regulatory compliance defense for warnings at the present time consequently should be limited to a very few special situations in which there are explicit, standardized guidelines to use in assessing the hazard warning.

Toward a National Warnings Policy

For the regulatory compliance defense to be of consequence for any more than a small segment of liability cases, Alan Schwartz and I have proposed a

38. One should demonstrate for each particular instance that the format and structure adopted adheres to the kind of vocabulary one would reasonably expect to be effective in that context. Comparisons within a class of products approved by this regulatory agency will often be instructive in this regard, since it will be indicative of the extent to which the warning departs from what has been achieved by other firms operating within a similar product context subject to identical regulatory constraints. However, compliance with regulatory guidelines that permit substantial variability should not necessarily be exculatory since one cannot always be assured that these warnings are as desirable on a risk-utility basis as other approaches that could have been adopted.

national warnings policy to establish a uniform national vocabulary for warnings. The general approach would be to establish standards for situations in which particular human hazard signal words, means of emphasis, indications of risk severity, and warning format would be used. This approach would extend across all contexts and would not be limited to a particular product group. Its effect would be a substantial broadening of efforts at standardization that have been undertaken by governmental groups such as the Food and Drug Administration and private organizations such as the American National Standards Institute.

There are several rationales for adopting this approach. The first dividend would be to establish objective criteria to serve as a reference point for assessing warnings. Rather than relying on an uncertain battle of experts with regard to the efficacy of a particular warning, one could simply assess whether a warning was in compliance with the guidelines of the national warnings policy. In particular, did the firm adopt the appropriate language and structure given the risk of the product?

A second advantage is that from an informational standpoint it will facilitate the ability of individuals to process information once we move to a common language and warnings format. As warnings efforts proliferate, there is a need for standardization of the language and the manner in which the information is presented. In the absence of such structure, it will be more difficult for individuals to process the information given to them. Moreover, even if it is processed, the content that is derived from the information may be different depending on the warnings format and wording because of the absence of a well established and common vocabulary. Thus, from the standpoint of communicating risks reliably to the recipient group, there is the advantage of commonality since we will establish a systematic means of communication. One of the purposes of warnings is to enable consumers to make across-product comparisons so that they can allocate both their product purchases and activity choices to better manage the risks in their lives. Establishing such commonality is essential for promoting more informed consumer choice.

Standardization alone is not the objective. In particular, in designing the national warnings vocabulary, we should take advantage of the capabilities scientific studies offer in developing sound and effective warnings formats.

Conclusion

Perhaps the most ironic aspect of the role of hazard warnings is that the net effect has been to expand enterprise liability rather than to contract it. From an economic standpoint, the role of hazard warnings should be to shift

40. The genesis of this proposal is the hazard warnings section of the American Law Institute report prepared by Schwartz and Viscusi (1990).
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responsibility for promoting safety from the producer to the consumer. Informing consumers about design risks at the time of purchase will enable them to make sounder decisions about the risks they wish to voluntarily incur. Providing information about appropriate precautions for a product augments the technological means of enhancing product safety by exploiting the capacity of consumers to increase the safety of products through proper use.

In practice, however, warnings doctrine does not function in this matter. Liability tests for hazard warnings have simply established a new way in which a product can fail the design defect test. Rather than contracting enterprise liability, hazard warnings have expanded firms’ liability.

Hazard warnings also have introduced another area of uncertainty in the litigation process. The warnings criteria that firms must meet remain nebulous. Moreover, there is no general recognition of the appropriate role of regulatory compliance. What is needed is a set of well specified guidelines to provide firms with a safe harbor once they undertake appropriate risk communication efforts. Detailed regulatory requirements, such as those for pharmaceuticals, represent one such reference point.

There is also a more general need to rationalize hazard warnings criteria for all products. This is not simply a matter of developing a common vocabulary. We must also ensure that the incentives for overwarning created by the courts will not lead to a dilution of the warnings that we wish to convey. The courts encourage too much prominence to minor risks and excessive proliferation of warnings across products. If everything in society is stamped “Hazardous,” then in effect no warnings will be given. The overall task of warnings policy is to be selective and to earmark those products that merit warnings and those that do not.

The best method of achieving a balanced warnings system is not to let the warnings systems emerge from a series of decentralized court cases in which firms seeking to limit their liability have an incentive to adopt an overly conservative approach. In the long run this overwarning will mute warnings’ impact. A preferable option would be to establish clear criteria that the firms should meet and which users of products can expect so that the presence or absence of a warning will have greater informational content. The major beneficiaries will be the product users themselves, who are now confronting an avalanche of warnings, health claims, and other risk-related information. Risk information is now widely disseminated but not effectively communicated.

A major theme that has emerged during the products liability crisis is that there has been an increasingly prevalent attitude in the courts that responsibility for accidents does not lie with the accident victim. Liability cases have turned into a search for the “deep pocket” rather than an examination of whether or not the producer met his obligations. The main message of hazard
warnings is that safety is a joint responsibility, not simply a responsibility of producers. A proper role of hazard warnings will increase the accountability of product users. However, before we can demand this accountability, the warnings systems that are used must do a more effective and comprehensive job in communicating risks to individuals in a manner that will enable them to better manage the risks in their lives.

References


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