Understanding "Safety"

When and Why a Lack of Warning May Not Equal a "Failure to Warn"

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With the right knowledge, a defense attorney can persuasively argue that an alleged failure to warn did not cause an accident.

In product liability litigation, a party may contend that the literature or warnings on a product downplayed the hazards associated with it, either by selecting the incorrect term for the level of hazard involved for a product warning (*i.e.*, using "Caution" instead of "Warning" or using "Warning" instead of "Danger"), by providing no warning regarding a particular hazard at all, or by not designing or guarding against a particular hazard. While in some cases such allegations may be completely on target, it is often the case that counsel either does not understand (or possibly simply would like for the *jury* not to understand) how appropriate terms are selected or which hazards can and should be addressed during the product design cycle. Appropriate warning terminology, as well as whether or not a warning, guard, or product design change is warranted, stems from a hazard-and risk analysis of a product, not simply from an elementary identification of the worst potential outcome that might arise from the product's improper use.

What would you think if someone told you that a commonly available product routinely resulted in the deaths of over 350 Americans every year when used properly, and yet the product was sold with no safety mechanisms, no guards, no instructions, and no warnings? Unsafe? Inherently dangerous? A menace to society? Examining the potential for fatal outcome based on the National Safety Council (NSC) "What Are the Odds of Dying?" chart reveals that this represents the approximate number of Americans that die each year by falling and drowning in their own bathtubs. Nearly 900

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people in the United States perish annually from falls from beds, chairs, and other furniture, while almost 575 die each year by strangling or suffocating themselves on bedclothes such as sheets and pillows.

Why is nothing done to address such "dangerous" products? Basing warning, guarding, or design change decisions on the worst possible outcome that might occur are simply nonviable. It rapidly leads to the conclusion that all products, no matter how benign, warrant the highest level of attention on the part of a user and a manufacturer and should either be labeled "Danger" or taken off the market entirely. Based on the often-cited "safety hierarchy," aren't hazards to be addressed through designing them out, guarding against them, or providing adequate warnings? For each of the products mentioned above, "safer" alternatives *do* exist. People can sit or sleep on the floor. They could adjust their thermostats for ideal comfort and get rid of sheets and blankets. Why not ban the "dangerous" bathtub and *make* everyone take showers?

To understand why such alternatives are unnecessary, some basic terminology must first be understood. The following definitions are taken directly from the National Safety Council *Accident Prevention Manual for Business & Industry* (12th ed.):

Risk—a measure of the probability of a hazards-related incident occurring and the severity of harm or damage that could result.

Hazard—the potential for harm: hazards include the characteristics of things and the actions or inactions of persons.

Safety—that state in which the risks are acceptable.

One key issue that must be kept in mind to understand the entire concept of *safety* realistically is that risks are to be reduced to an *acceptable* level; they do not need to be completely eliminated for a product to be "safe." The NSC *Accident Prevention Manual* expresses this in these words: "Minimum risk is achieved when all risks deriving from hazards are at a realistic minimum, and acceptable. Minimum risk does not mean zero risk, which is unobtainable." This point is also acknowledged in ANSI B11.TR3-2000 (ANSI Technical Report - *Risk Assessment and Risk Reduction - A Guide to Estimate, Evaluate and Reduce Risks Associated with Machine Tools),* which categorically states, "This technical report explicitly recognizes that zero risk is virtually unattainable."

In litigation, in many product liability cases a party will vaguely assert that a manufacturer or a supplier is liable for failure to warn about the operation, maintenance, use, inspection, or repair of a product, or a combination of these. From the very beginning of the litigation, to ascertain the nature of and basis for these claims, such claims must be challenged in responsive pleadings and throughout discovery in discovery requests and depositions.

Through interrogatories, these parties should be compelled to describe the precise respect in which they claim that a manufacturer is at fault for failing to warn, how a manufacturer's alleged failure to warn is causally related to the accident or injuries, how they claim that a manufacturer could have properly warned or instructed or both, and they should identify the specific warnings that could and should have been provided and how these would have prevented or mitigated an accident or injuries or both. Deposition testimony can also be elicited to disprove the causation element necessary in failure-to-warn claims. These strategies are discussed more fully below.

Hazard Analysis of "Dangerous" Products

The truth of the matter is that none of the previously mentioned "dangerous" products meet objective criteria for any type of intervention based on hazard analyses. ANSI B11.TR3-2000, as well as ANSI Z535.4-2007 (the American National Standard for Product Safety Signs and Labels), and ANSI Z535.6-2006 (the American National Standard for Product Safety Information in Product Manuals, Instructions, and Other Collateral Materials), provide a process overview for performing a risk estimate with regard to a particular product. This process is not entirely an objective, mathematical exercise. Both of the warnings standards expressly note that

> [r]isk estimation involves (a) considering the probability and severity of harm that can result from a hazardous situation, and (b) combining these estimates to determine the risk. While quantitative risk assessment is possible in certain limited circumstances, only qualitative risk estimates are possible in most cases. For the purpose of safety messages classification (*i.e.*, assigning a signal word and safety color, and determining whether the safety alert symbol is appropriate), qualitative risk estimation is commonplace and generally appropriate.

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Table 1. Mishap severity categories

Category	Severity of harm
Catastrophic	Death or permanently disabling injury or illness (unable to return to work)
Serious	Severe debilitating injury or illness (able to return to work at some point)
Moderate	Significant injury or illness requiring more than first aid (able to return to same job)
Minor	No injury or slight injury requiring no more than first aid (little or no lost work time)

Source: ANSI B11-TR3 (2000).

Table 2. Probability level example

Category	Severity of Harm
Very likely	Near certain to occur
Likely	May occur
Unlikely	Not likely to occur
Remote	So unlikely as to be near zero

Source: ANSI B11.TR3.

Risk associated with a product is a function of three elements: (1) the worst *credible* (not possible) severity of harm should an accident occur; (2) the probability of an accident resulting if the hazardous situation should arise; and (3) the probability of the worst credible severity of harm occurring. None of the cited standards define the term "credible severity of harm," or determine precisely which categories of outcome must be evaluated, but numerous other sources provide perspective on these points. Table 1 presents various categories of potential outcome taken from ANSI B11.TR3 and a narrative description of their consequences.

Table 2 is also from ANSI B11.TR3 and details frequency categories for evaluating an accident's likelihood of occurring (in this case expressed in terms of probability of accident as a function of number of exposures.)

Unfortunately, Table 2 provides only narrative qualitative rather than quantitative descriptions of the likelihood of occurrence, and it gives no perspective on whether someone is evaluating the likelihood of an event for a single product or across the entire group of products that are in the field. Table 3 is a similar data set taken from MIL-STD-882D-2000 (one of the source documents for the ANSI report); this table shows equivalent likelihood of occurrence categories routinely used by the American military when performing hazard analyses, and it does include numeric norms and qualitative information that provides a perspective on the evaluation of hazards across the total number of the product that is in use rather than for an individual exemplar of that product. It should be noted that it is common to assign probabilities to various outcome events in a heuristic fashion, rather than based on some absolute normative values, since historical data including exposure rate is often not available. See Table 3.

Table 3. Mishap probability levels

Description*	Level	Specific individual item	Fleet or inventory**
Frequent	A	Likely to occur often in the life of an item, with a probability of occurrence greater than 10-1 in that life.	Continuously experienced.
Probable	B	Will occur several times in the life of an item, with a probability of occurrence less than 10-1 but greater than 10-2 in that life.	Will occur frequently.
Occasional	C	Likely to occur sometime in the life of an item, with a probability of occurrence less than 10-2 but greater than 10-3 in that life.	Will occur several times.
Remote	D	Unlikely but possible to occur in the life of an item, with a probability of occurrence less than 10-3 but greater than 10-6 in that life.	Unlikely, but can reasonably be expected to occur.
Improbable	E	So unlikely, it can be assumed occurrence may not be experienced, with a probability of occurrence less than 10-6 in that life.	Unlikely to occur, but possible.

* Definitions of descriptive words may have to be modified based on quantity of items involved.
**The expected size of the fleet or inventory should be defined prior to accomplishing an assessment of the system.
Source: MIL-STD-882D (2000).

Table 4. Risk estimation matrix

Probability of occurrence	Severity of harm			
	Catastrophic	Serious	Moderate	Minor
Very likely	High	High	High	Medium
Likely	High	High	Medium	Low
Unlikely	Medium	Medium	Low	Negligible
Remote	Low	Low	Negligible	Negligible

Source: ANSI B11.TR3.

Table 5. Risk reduction approaches compared

Approach	Impact on accident severity	Impact on exposure rate
Design hazards out of product	Greatest level of impact	Little
Safeguards in design	Little	Greatest level of impact
Information for use	None	Little
User implemented safeguards	Little, if any	Greatest for hazards covered by added safeguards
Safe working procedures	None	Little
Training/PPE	Some	Little

Source: Derived from ANSI B11-TR3-2000.

The risk assessment process yields a risk level—the probability of occurrence of harm and the severity of that harm. After the risk levels and probabilities of occurrence associated with a device are determined, a matrix is developed assigning each combination a relative weight for further evaluation. The categorical values shown in Table 4 are representative but not necessarily typical of any particular environment or equipment. Matrices with different weightings and outcomes for the

same probability of occurrence and severity of harm are possible and can legitimately be used.

It should be noted that the values of the categories are not definitive, and they do *not* reflect the manner in which a particular hazard should most appropriately be addressed, but rather whether they should be addressed at all and the priority for doing so. If a risk is determined to be within the "tolerable" range, no action is necessary. If a risk level does not fall within the tolerable range, it is necessary to reduce that risk by implementing some type of protective strategy. Reduction of risk is the result of the application of one or more protective measures. The type of protective measure is determined by the nature of the task and its associated hazard or hazards for the machine or product under consideration and should be selected to provide the desired degree and type of risk reduction. The risk reduction process is complete when protective measures are applied and a tolerable risk has been achieved for both the identified task and hazard combinations and the machine or product as a whole.

Examining Table 4 reveals that even potentially fatal or permanently disabling hazards may not reach the "High" or even "Medium" priority levels if the likelihood of their occurrence is sufficiently low. This is true even of accidents that fall into probability categories that are *likely* to occur across the entire inventory of similar products.

Returning to our earlier examples, given the current estimated U.S. population of 307 million and one daily exposure per person, this leads to a likelihood of one chance in 195 million that someone would be "bumped off" by those "killer" sheets and pillows or one chance in 320 million that someone would be done in by that "dangerous" bathtub on any particular day. Someone has a considerably better chance of winning the lottery on a single ticket. Despite the low relative chance that an accident would accompany an exposure, with a sufficiently large population, accidents can and do occur.

Acceptable Risk Reduction Activity

If it is determined that some risk reduction activity regarding a product is necessary based on the hazard assessment, the choice of how to reduce the risk is not necessarily clear-cut or straightforward. By definition, any "fix" for a hazard that eliminates the utility of a product is unacceptable. For instance, a dull knife would likely prevent an individual from cutting him- or herself, but it would be of little or no utility. In practice, there is a widely accepted heuristic hierarchy of risk reduction methods.

1. Redesign to reduce risk.
2. Incorporate safety devices.
3. Provide warnings.
4. Develop and implement operating procedures and employee training programs.
5. Use personal protective equipment.

As noted earlier, the end goal is not to eliminate *all* residual risk from a product, but rather to reduce the risk to an *acceptable* level. Often, a combination of techniques will prove most effective for accomplishing this goal. Higher levels within the hierarchy are *generally* preferred due to their greater effectiveness in reducing accident severity or exposure rate. All of the methods, however, are not equally effective against all aspects of potential hazards. Further, the lower the severity of a hazard or the likelihood of its occurrence, the less rational, reasonable, and economically viable major design changes become. Table 5 provides a general comparison regarding the different approaches and their effects on accident severity and hazard exposure.

The nature of the design and the guarding design processes are beyond the scope of this particular article, but some information about warnings and how they should be formatted is germane to a discussion of risk assessment. The primary purpose of warnings is to provide information about potential hazards to product users. An additional purpose may be to remind users of known dangers that are not "open and obvious" and are only infrequently encountered; warnings regarding a single, otherwise undifferentiated power-operated door that operates at three times normal speed in a facility with many similar doors operating at normal speed may be of value, but warnings regarding the possibility of drowning in water or being hit by moving cars when crossing a roadway are not. According to *The Sign Maze: Approaches to the Development of Signs, Labels, Markings and Instruction Manuals,* a publication by the American Society of Safety Engineers, warnings are desirable when the hazard is foreseeable and it involves the following:

1. The hazard is, by definition, dangerous;
2. The danger posed by the hazard is or should be known to the producer, manufacturer, supplier, or facility manager;
3. The danger is not one that is obvious, known, or readily discoverable by the user; and
4. The danger is not one that arises because the product or substance is put to some irrational use.

The distinction between abnormal use and a "reasonably foreseeable" hazard can be subtle. One definition is that an action taken by many users can rationally be considered reasonably foreseeable, while an action that represents isolated incidents by only a few users by definition constitutes abnormal use. Unfortunately, this definition can only be applied after the device has been available long enough to allow measurement of the frequency of such incidents. An alternative approach is to use the dictionary definition of the word "foreseeable": "that which a person of ordinary prudence would expect to occur or exist under the circumstances." The same source defines the word *"expect"* as meaning *"regard as likely to happen."* These definitions are close in accordance with Black's Law Dictionary (6th ed.), which uses the phrase "That which is objectively reasonable to expect, not merely what might conceivably occur" when describing the term "foreseeability." From this, it can be said that a producer or a supplier of a product is responsible for determining how their product is *likely* to be used or misused, not how it can *conceivably* be misused.

Failure-to-Warn Litigation

The analysis of a failure to warn claim in litigation, however, varies from state to state. In each state, particular statutory and case authority should be consulted. Indeed, in some states "foreseeability" is not relevant in a strict product liability claim.

The analysis of whether a hazard is "foreseeable" and whether a product warning is sufficient to protect against that hazard, however, will vary depending on whether

a jurisdiction follows the Restatement (Second) of Torts or the Restatement (Third) of Torts. Under the Restatement (Second), a product accompanied by an appropriate warning is not in a defective condition. Under the Restatement (Third), however, determining whether a product warning is sufficient would be analyzed in relation to whether a safer product design exists that would not require a warning.

If a behavior is sufficiently unlikely—whether due to end user knowledge, simple caution, or sheer irrationality—the behavior will more likely than not fall into the "low" or "negligible" risk category.

Whether the Restatement (Second) or (Third) of Torts is followed, in defending a failure-to-warn claim, a defense attorney must first make it clear, if appropriate, that adequate warnings and instructions were supplied. Under the Restatement (Second) of Torts, a product accompanied by a warning that the product is safe for use if the warning is followed, is not in a defective condition. *See, e.g., Fleck v. KDI Sylvan Pools, Inc.,* 981 F.2d 127 (3d Cir. 1992); *Ilosky v. Michelin Tire Corp.,* 307 S.E.2d 603 (W. Va. 1983). A manufacturer has a duty to give a reasonable warning and instruction about the dangers inherent or reasonably foreseeable in a product's use. *See, e.g., Waering v. BASF Corp.,* 146 F. Supp. 2d 675 (M.D. Pa. 2001); *Morningstar v. Black & Decker Mfg. Co.,* 253 S.E.2d 666 (W. Va. 1979).

Liability cannot be imposed for failing to warn or instruct, however, if the danger is generally known and recognized, or should be known. *See, e.g., Brown v. Caterpillar Tractor Co.,* 741 F.2d 656 (3d Cir. 1984); *Painter v. Momentum Energy Corp.,* 271 S.W.3d 388, 410 (Tex. App. – El Paso 2008)(citing *Caterpillar Inc. v. Shears*, 911 S.W.2d 379, 382 (Tex. 1995)). A manufacturer simply has no duty to warn or instruct if a user of a product or the product user's employer is knowledgeable or reasonably should be knowledgeable in the handling or use of the product. In other words, a manufacturer should be able to assume the mastery of basic operations by expert or skilled professionals in an industry, and the manufacturer owes no duty to warn or instruct such persons on how to perform basic operations in their industry of which they are aware or should be aware. *O'Neal v. Celanese Corp.*, 10 F.3d 249 (4th Cir. 1993); *Brown*, 741 F.2d 656.

When a warning or instruction is given, a manufacturer may also reasonably assume that these warnings and instructions will be read and followed. A product accompanied by a warning or instruction, which is safe for use if the warning or instruction is followed, is not in a defective condition. Restatement (Second) of Torts, §402A, Comment J. For example, in confronting a failure-to-warn claim, defense attorneys should underscore that at the time that a product left their control, it was equipped with operator's and user's manuals or instructions and labels or placards fully and completely informing operators or users of the proper and safe operation and use of the product.

Assessing a Failure-to-Warn Claim in Discovery

In applying these concepts, relevant facts to develop and consider in discovery in assessing a failure to warn claim, include the following:

1. Was injured party an expert or skilled in the subject industry? How long has he or she worked in the industry and with the product? Develop his or her expertise with and knowledge about the product.
2. Did the injured party receive any training regarding the proper and safe operation and use of the product? If so, who provided that training, how long did it last, what type of training was provided, and specifically, what instructions did he or she receive? Are there documents or records that confirm this training?
3. After receiving his or her training, was the injured party satisfied that he or she had received sufficient training to allow him or her to operate and use the product properly and safely? As a result of his or her training, did the injured party understand the importance of these instructions and that if they were not followed he or she could be seriously injured or even killed, depending on the circumstances?
4. Confirm whether or not the injured party's training included the warnings or instructions contained in the operators or instruction manual and written materials provided with or on the product.
5. Confirm whether the injured party, during his or her training or any time before the accident, was provided with the operator or instruction manual or written instructions regarding the proper and safe operation of the product.
6. If not, before the accident did the injured party ever request any written manuals or instructions regarding the proper and safe operation and use of the product from his or her employer or the manufacturer?
7. If the injured party did receive written manuals or instructions, did he or she read them or look for and read the labels or placards on the product itself?
8. If the injured party did not look for and read the written operator or instruction manual or the labels and placards that were provided with the product or on the product before his or her accident, the causation element of the failure-to-warn claim is severely damaged, if not defeated. Indeed, if he or she did not look for and read what was provided, he or she would not have looked for and read what he or she claims should have been provided.
9. If the injured party did read the written operator or instruction manual or product labels and placards, or a combination of these, however, does he or she have any criticisms of the written instructions or labels? If so, what are they?
10. If the injured party did read the warnings or instructions that were provided with the product, confirm that he or she understood them and that he or

she knew that if they were not followed, he or she could be severely injured or even killed.

Expert Implications

If it can be shown that warnings were issued, to prove a failure-to-warn claim expert evidence must also be produced that the warnings and instructions issued were inadequate or deficient or that additional or other warnings or instructions should have been provided. *See, e.g., Toth v. Economy Forms Corp.,* 571 A.2d 420 (Pa. Super. 1990). Such expert testimony can be countered by eliciting admissions that the expert does not know if any proposed alternative warnings or instructions, had they been provided, would have prevented the accident. In addition, questioning an expert should include asking whether, even with the proposed warning or instruction, to prevent accidents of the kind making the basis of the litigation, an operator must still read, understand, and follow the warning or instruction. Testimony may also be elicited that shows that accidents can still occur if such warnings or instructions are not read or followed.

In addition, an expert should be questioned about whether he or she designed, drafted, or wrote any of the warnings that he or she claims should have been provided, as well as their size, location, content, color, and whether he or she conducted any testing, surveys, or research to confirm or validate his or her opinion that the proposed labels, instructions, or warnings would have been read, understood, and followed had they been present on the product.

A case from the United States Court of Appeals for the Seventh Circuit supports the reasoning behind this line of questioning. In *Bourelle v. Crown Equipment Corp.*, 220 F.3d 532 (7th Cir. 2000), plaintiffs were injured in the course of their employment by an allegedly defectively designed forklift. The plaintiffs' expert's opinions were held inadmissible and stricken. To recover their alleged damages, the plaintiffs sued the forklift's manufacturer, Crown, for defective design and inadequate warnings. The plaintiffs' expert's opinions were based on the following work: reading the depositions of the plaintiffs and 10 other witnesses and reviewing Crown's manufacturing and service documents for the forklift, Crown's sales brochures, a training manual, and engineering drawings for the forklift. *Id.* at 534–35. On merely this basis, plaintiffs' expert, Daniel Pacheco, concluded that the forklift was defective because it was designed with inadequate guarding and equipped with insufficient warnings. *Id.*

In striking these opinions, the district court emphasized that the plaintiffs' expert tested nothing. With respect to his theory that Crown had warned inadequately, the trial court stressed that the expert had not designed or drafted the warning that he contended should have been present. *Id.* at 535. On appeal, the Seventh Circuit affirmed, finding that the trial court had not abused its discretion in excluding the expert's testimony. In reviewing the trial court's decision, the Seventh Circuit examined whether or not the expert's opinions were derived by the scientific method. *Id.* at 536–37. After considering the sparse work that the plaintiffs' expert had done, the Seventh Circuit agreed with the trial court that the expert's opinions were "nothing more than speculation and were thus unreliable." *Id.* at 538.

The Seventh Circuit, affirming the trial court's ruling excluding the expert's claim of inadequate warnings, held:

> Like his proposed design, Pacheco's failure to even draft a proposed alternative warning for the [forklift's] operation manual renders his opinion regarding the alleged inadequacy of Crown's existing warning concerning the risk of pallets entering the [forklift] operator's compartment to be unreliable.… The fact that Pacheco never even drafted a proposed warning renders his opinion akin to "talking off the cuff" and not acceptable methodology.

Id. at 539. Accordingly, the court of appeals concluded that the trial court did not abuse its discretion in excluding as unreliable the plaintiffs' expert's opinion regarding a warning for the forklift.

Restatement (Third) of Torts Approach

This analysis might change, however, under the Restatement (Third) of Torts. Under section 2 of the Restatement (Third) of Torts, 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.

Although Comment d to section 2 of the Restatement (Third) of Torts is favorable to manufacturers by requiring a plaintiff to show that a reasonable alternative product design exists, Comment l to section 2, however, seems to create a preference for a safer product design over instructions and warnings. Comment l states:

> Reasonable design and instructions or warnings both play important roles in the production and distribution of reasonably safe products. In general, when a safer design can reasonably be implemented and risks can reasonably be designed out of a product, adoption of the safer design is required over a warning that leaves a significant residuum of such risks. For example, instructions and warnings may be ineffective because users of the product may not be adequately reached, may be likely to be inattentive or may be insufficiently motivated to follow the instructions or heed the warnings. However, when an alternative design to avoid risks cannot reasonably be implemented, adequate instructions and warnings will normally be sufficient to render the product reasonably safe. Warnings

Many jurisdictions operate under the supposition that product users actively seek information and will automatically comply with warnings if they are provided.

are not, however, a substitute for the provision of a reasonably safe design.

An application of Comment l to section 2 of the Restatement (Third) of Torts can be found in *Uniroyal Goodrich Tire Co. v. Martinez*, 977 S.W.2d 328 (Tex. 1998) (declining to follow Comment j to the Restatement (Second) of Torts and relying on Comment l to §2 of the Restatement (Third) of Torts to affirm a finding of defective design even where plaintiff admitted that the product warning was effective, he had seen the warning, and that, if he had heeded the warning, he would not have been injured). Comment l to section 2 of the Restatement (Third) of Torts may prove to be troublesome to manufacturers when they must defend failure-to-warn claims.

Effectiveness of Warnings

Warnings should thus be targeted at dangerous behaviors that are (1) known or anticipated by a producer; (2) relatively likely to occur; and (3) unrecognized by an individual as being dangerous. The need to warn regarding a particular hazard can be assessed through the risk assessment methodology discussed above. If a behavior is sufficiently unlikely—whether due to end user knowledge, simple caution, or sheer irrationality—the behavior will more likely than not fall into the "low" or "negligible" risk category. It might reasonably be determined that a warning would be unlikely to serve any purpose, primarily since it could have no effect on the *severity* of the potential incident and little effect on the *likelihood* of occurrence.

Regardless of the effectiveness of warnings, they can be appropriate and useful when users are unaware of either the nature or degree of hazard associated with a particular product or action. Given this, one of the primary cues provided to a warning reader about the level of hazard associated with a product-action combination is the signal word used as a cue, such as "Danger," "Caution," or "Warning." *Or is it?*

Selecting Terms and Language

ANSI Z535.4 provides guidance on choosing the appropriate term to be used. When no federal, state, or local government regulation, standard, or guideline specifies a particular signal word, selecting the signal word is to be done in accordance with the following definitions:

- "Danger": Indicates a hazardous situation that will result in death or serious injury if it is not avoided. This signal word is to be limited to the most extreme situations.
- "Warning": Indicates a hazardous situation that could result in death or serious injury if it is not avoided.
- "Caution": Indicates a potentially hazardous situation that may result in minor or moderate injury if it is not avoided. It may also be used to alert against unsafe practices.
- "Notice": Is the preferred signal word to address practices not related to personal injury.

"Caution" without the "safety alert" symbol may be used to indicate a message not related to personal injury. On the other hand, the term "Caution" is being phased out of the standard for hazards not related to a personal injury.

The "safety alert" symbol referred to above consists of a triangle with an exclamation point contained within it appearing immediately preceding the signal word in the warning when potential for personal injury exists. The practical usefulness of this particular designator is questionable because although individuals in the warnings research and standards development communities are familiar with what it stands for, most of the general public seem unfamiliar with this symbol.

Selecting a particular signal word thus depends on identifying the worst *credible* harm that could result should an accident occur, the actual probability that the worst credible harm will indeed result as a function of an accident, and the probability that an accident will occur at all if the safety message is ignored. The likelihood of an accident resulting from not complying with a safety message is evaluated by placing it in one of two possible categories: *will* occur, indicating that an event is expected to happen with near certainty; or *could* occur, indicating that an event is possible, but not nearly certain. Given the level of harm and likelihood data, the appropriate signal word is then selected from the matrix shown in Table 6.

Even if consequences of an accident are likely to be catastrophic (*i.e.*, fatal or permanently disabling), the word "Danger" is *not* used unless it is *certain* that the consequences will result if the hazardous behavior is performed. For example, an extremely high-voltage bus bar would legit-

Table 6. Matrix for selecting appropriate signal word based on hazard and probability of outcome.

		Probability of accident if hazardous situation is not avoided	
		Will	**Could**
Probability of death or serious injury if accident occurs	**Will**	DANGER	WARNING
	Could	WARNING	WARNING
Worst credible severity of harm is moderate or minor injury		CAUTION	CAUTION
Worst credible severity of harm is property damage		NOTICE (preferred) CAUTION (optional)	NOTICE (preferred) CAUTION (optional)

Source: (ANSI Z535.4-2007.

imately have a sign near it that read, "Danger" (*i.e.*, you *will* be shocked if you touch the bus bar, and you *will*, most probably, not survive the experience), while a slippery floor could legitimately only have a sign reading "Caution" (*i.e.*, you *might* slip if you walk on this floor, and even if you do slip, you are *unlikely* to suffer life threatening injuries). The fact that you could possibly slip, fall, and impale yourself on a mechanical pencil that fell from your pocket in the latter case is not germane. The threat while *conceivable* is simply not credible or likely to occur.

It is often argued that if there is *any* potential for an injury resulting from a product to be either fatal or disabling, then "Danger" is the appropriate signal word. There are two problems with such logic. First, misuse of *any* product could theoretically result in potential death or injury given the appropriate scenario. A tuna tin dropped from the top of a tall building could easily cause brain injury if it struck someone on the sidewalk below. One of the authors of this article has actually seen a warning on a portable CD player alerting users that they should not use the device as a projectile in a catapult. Neither of these are appropriate subjects for warnings because the hazards that they address are not *credible*, even though they may be theoretically *possible*. Further, if someone did provide a warning regarding a wildly improbable event, then, by logical extension, a requirement would then exist to provide warnings regarding *every* other potential negative event with a similar or greater probability of occurrence. The resulting proliferation of "warnings" regarding events with essentially little or no potential for occurrence in reality would rapidly overload the willingness of a product user to wind his or her way through the mass of verbiage to identify those eventualities that had a credible potential to occur, creating a "warnings dilution" effect, reminiscent of Aesop's fable "The Boy Who Cried Wolf."

Second, the purpose of a signal word is to draw the attention of a reader rapidly by prioritizing those warnings that are most critical for a reader's safety. Overuse of a high-level signal word serves to desensitize a reader quickly to that word. If every warning is marked with the word "Danger," then there is no way to discern quickly which hazards are most threatening and direct a reader's attention to those, without having to winnow through the mass of obvious or unlikely eventualities that are also addressed.

A legal argument focusing on the selection of an inappropriate signal word is likely, however, to be "much ado about nothing." Research studies have repeatedly demonstrated that the choice of signal word, in general, does *not* influence users' levels of perceived hazardousness of products or the perceived consequences of warned against behaviors, except for words at the extreme ends of the spectrum (*i.e.*, "Danger" as opposed to "Note"). Readers perceive no significant difference between these pairings: "Danger" and "Warning"; "Danger" and "Caution"; or "Warning" and "Caution." Much the same is true for the words "Flammable" and "Combustible."

Product User's Risk-taking Behavior Explained

Many jurisdictions operate under the supposition that product users actively seek information and will automatically comply with warnings if they are provided. Such a view is largely contradicted by findings from published research studies and analyses of industrial and product accidents. In a substantial number of the latter, it is clear that the injured parties were well aware of safe operating procedures but chose to disregard them for reasons that seemed to be appropriate to them at the time. It is clear in such cases that a lack of adequate information was not the cause of the accidents, and thus supplying more would not have prevented them from occurring.

To understand the viability of warnings or instructions, it is necessary to understand the way that product users evaluate risk as opposed to the way that product manufacturers do it. Warnings are predicated on the idea that product users are unaware that a particular behavior has the potential for negative consequences and that providing the appropriate information will result in changes in behavior, thus reducing accident likelihood. While this is true in some cases, this is far from being a universal truth. In many, if not most, instances, product users are fully aware of appropriate behavior and the potential consequences of their actions, yet they still elect to engage in risk-taking behavior.

One good perspective that can be used to evaluate user-product interaction is based on simple decision making. This approach relies on the following premises:

1. Safety precautions are generally correctly understood and interpreted by users.

An important point to remember is that the probability of the negative consequence in this analysis is *subjectively* assessed by the individual, often based on previous personal experience.

2. If a user disregards a safety precaution, he or she has made a choice to do so.
3. Although the decision to disregard a precaution may not appear to be rational to a product provider, it is based on some perceived benefit to themselves by the users.
4. Most disregarded precautions do not end in disaster, so continuing to disregard them in the future is a behavior reinforced by the benefit gained by it.

The reinforcement derived by a user in such cases can occur in the form of either the bestowal of a "reward" (a positive outcome) or the elimination of a "cost." "Cost of compliance" is one of the most important factors in predicting potential warning compliance. Research has repeatedly demonstrated that virtually any type of discomfort, restriction of movement or freedom, or other encumbrance can serve as a barrier to warning compliance. This includes the simple fact that behaving *un*safely is sometimes simply more pleasurable or rewarding than behaving safely. Adolescents and young adults, in particular, frequently place a premium on risk-taking for its own

sake. Providing warnings to them has often been shown to result in a "boomerang effect" in which the hazardous behavior becomes *more* rather than less prevalent.

One of the more obvious conclusions that can be reached when examining behaviors resulting in accidents is that subjective assessment of risk and the actual hazard of a behavior are not linearly related to each other. There are two current general theories regarding risk acceptance on the part of individuals. The first is more or less similar to a simple cost-benefit type of analysis. According to this theory, the perceived risk in a situation is a function of both the perceived likelihood and the seriousness of the hazardous consequence in comparison to the utility attached by the individual to the accomplishment of the behavior. As the perceived likelihood or seriousness of the consequence increases, the likelihood of the behavior occurring theoretically diminishes, assuming that the utility of performing the behavior remains constant. The primary purpose of a product warning is to acquaint an individual with consequences of which he or she may be unaware; if an individual is already aware of the consequences, this information can, by definition, be only of limited value (*e.g.*, possibly as a reminder). An important point to remember is that the probability of the negative consequence in this analysis is *subjectively* assessed by the individual, often based on previous personal experience. As self-confidence increases, which occurs as a function of increased experience with the situation, perceived risk usually diminishes, potentially to the point of zero perceived risk.

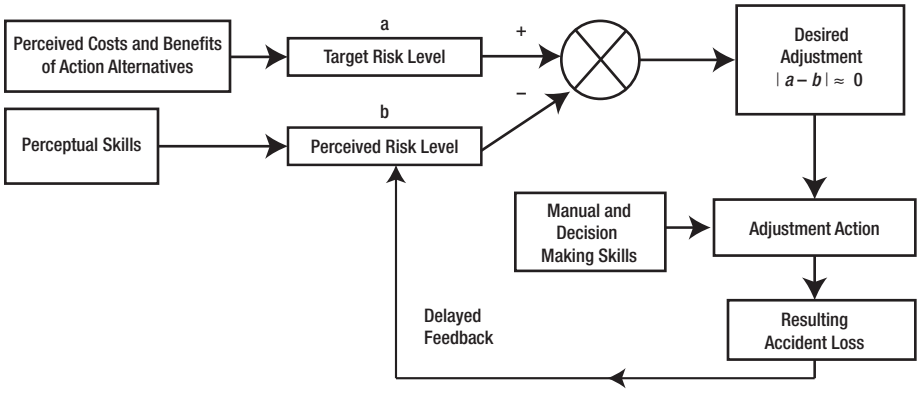
Consider the task of crossing a busy street. Most of us are taught relatively early to look for oncoming traffic before crossing. Why? The purpose of checking is to ascertain whether or not there is adequate time for us to make it to the other side with an ample margin of safety before the approaching vehicles reach our position. As we mature from early childhood, the amount of time that it requires to cross the street decreases, the quality of our estimates of both crossing time and the time that it will take approaching vehicles to reach us improve, and the perceived likelihood of negative factors increasing our crossing time (*e.g.*, tripping and falling) diminishes. The combination of all factors means that we regard crossing the street as being relatively safe, as long as we look first, and it is likely that we are much more willing as adults to cross with less space between ourselves and oncoming traffic than we did as children.

Placing a sign on every street corner with the warning "DANGER: Cars can squash you flat. An estimated 1 in a million crossers don't make it. Look both ways for oncoming cars" is unlikely to have any practical effect on safety, primarily because the potential consequences of *not* making it are open and obvious to anyone capable of comprehending the sign, and the probability of occurrence is sufficiently low that many if not most individuals would regard it to be effectively zero as long as "sufficient" time to make it across the street was allowed. Further, the need to modify the proposed "warning" to address such variables as "Trucks may squash you," "Buses may squash you," "Steamrollers may squash you" is unnecessary; the general term "cars" in this case encompasses the other less common cases. Most importantly, the hazard (being "squashed" while crossing) is already known to those capable of reading the sign to begin with. Such "warning" signs could have no utility for those that cannot read them at all (*e.g.*, young children or the blind).

An alternative theory is that of *risk homeostasis*, which postulates that in general, an individual determines an "acceptable" level of subjectively estimated risk for any particular task in exchange for the benefits that he or she expects to receive for undertaking the activity. Behavior is based on a balance between the two. If the level of risk associated with an activity is assessed as being greater than the acceptable level, people tend to exercise greater levels of caution than would otherwise be the case. The flip-side of this is also true: if the level of risk is assessed as being *less* than the acceptable level, individuals may tend to engage in actions that *increase* their level of risk-taking as long as there is any tangible benefit to doing so. Individuals tend to regulate their behavior to maintain a homeostasis (balance) between risk-exposure and risk-avoidance at what they determine to be an optimal (acceptable) level between risk and return.

Again, it is critical to remember that the level of risk associated with an activity is subjectively, not objectively, determined. Consider the example of a driver who routinely drives 5 to 10 miles per hour over the speed limit. The benefit associated with such behavior is decreased travel time, while the primary risk of such behavior is the potential for being pulled over and ticketed for speeding. Such drivers can go for long periods without experiencing any penalties and enjoying the benefits of their actions. Consequently, their subjective perception of the risk associated with their action (*i.e.*, likelihood of occurrence) decreases the longer they go without being ticketed, potentially leading them to further *increase* their normal travel speed. Eventually, they are caught and fined. Their subjective assessment of the likelihood of encountering the potential risk then increases, normally resulting in a reversion to the speed limit for some period of time. Objectively, the risk associ-

Figure 1. Risk homeostasis model.



Source: Adapted from G.J.S. Wilde, Target Risk 2: A New Psychology of Safety and Health (2001).

ated with being caught speeding does not increase simply as a function of the short time since last ticket (indeed, in the immediate short-term it actually decreases, since the location of the local traffic control authority is now known to them), though a change in risk-taking behavior has resulted. The same type of behavior occurs in numerous other daily activities. The process itself is displayed graphically in Figure 1.

Under both theories, two variables of critical importance are the perceived risk level and the perceived skill level, which has a direct relationship with likelihood of encountering the hazard. Studies have shown that some of the factors that decrease the perceived level of risk of an activity are familiarity, voluntary versus. involuntary exposure, hazard comprehension, and the controllability of the hazard. All of these factors are, to a great deal, a function of an assessor's level of experience with the hazard. Further, when individuals commonly expose themselves to a hazard and experience no harm, a type of "risk habituation" begins to set in. Then the perceived level of risk drops even further, and complacency about their capability to successfully perform risky activities increases. Experienced drivers, for example, routinely overestimate their abilities; most surveys indicate that the overwhelming majority of drivers rate their capabilities as "above average," while few rate themselves as "below average." In reality, of course, more than half of the population cannot be "above average."

A person inexperienced with using a particular product has little basis for judgment regarding the risk associated with it other than through training, the information that he or she receives with the product, or his or her previous experience with other similar products. Under normal circumstances then, risk estimates of novice product users could be expected to be higher than those of their experienced counterparts due to a lack of knowledge or previous benign experience with a product. Further, an inexperienced individual is less likely to be complacent regarding his or her level of skill in using a product. The combination of these factors would be expected to produce a higher degree of risk avoidance behavior among less familiar product users.

A skilled product user on the other hand, may have an extensive baseline regarding accident likelihood from his or her own previous experience using a product, and his or her assessment of the likelihood of experiencing negative consequences from a particular behavior may be far lower than that of a less experienced individual. Further, an experienced user is more likely to have an inflated assessment of his or her own level of competency in dealing with any potential accident should it occur, based on the fact that he or she has always successfully avoided any consequences in the past. These factors in combination would be expected to result in increased risk-taking behavior by experienced product users.

Under the risk homeostasis theory, warnings may or may not have a positive effect depending on the degree to which they support or conflict with a particular individual's risk assessment of a particular product and action combination. If a warning provides new information that supports a permanent change in the perceived likelihood of experiencing a negative outcome, the new information may be beneficial. The effect of providing information that has *already* been included in an individual's assessment of the potential for experiencing negative consequences (*e.g.*, something either already known through experience or training, or being obvious) would be nil.

An interesting corollary to the risk homeostasis perspective involves the concept of behavioral adaptation. As noted earlier, as perceived risk decreases, risk-taking behavior would be expected to rise as long as there was a positive benefit to be derived from doing so. What then would be the expected effect of introducing a new safety feature into an existing product? If the theory is correct, it should prove difficult in the extreme to increase overall safety through the design process once foreseeable *unintentional* interactions with a hazard have been designed out or guarded against. If a product were to be redesigned to eliminate a potential hazard that results from high-risk user behavior, such behavior then would become *acceptable* rather than exceptional. Even under the cost-benefit model discussed above, as an individual's perception of the risk associated with an activity drops to zero (or at least a very low level), the likelihood of the behavior being engaged in increases (or at least the drive to avoid such behaviors drops precipitously).

One potential example of this effect involves the incorporation of guards on power saws. Well before power saw designs incorporated these guards, the majority of saw users were well aware of the potential hazard of willingly placing their hands in close proximity to a saw blade; most tried actively to avoid such an eventuality. Once the guards were included on the saws, however, the rationale for keeping the hands completely away from a blade area was reduced. It is, however, extremely difficult for such guards to cover the actual point of operation on these devices (*i.e.*, the work piece being cut still has to reach the blade). The purpose of most safeguarding is to reduce the likelihood that an operator will *inadvertently*, rather than intentionally, enter a danger area. If a user's focus on actively avoiding a now-guarded zone diminishes, there is likely to be a greater level of exposure to the residual hazard, and the protective value of a guard is at least partially negated. Similar examples exist in other application areas such as hazards to electrical workers knowingly working with "hot" wiring while using insulated tools. It is unlikely that such workers would expose themselves to this risk if their tools were *not* insulated (*i.e.*, behavioral adaptation has occurred.)

One particularly interesting type of behavioral adaptation is that which results from design changes that product users *perceive* to increase safety but that may not. or may not increase safety in the manner or amount that users believe. An example of this would be the availability of 4-wheel or all-wheel drive on many newer vehicles. The perceived superiority of the traction available with such vehicles might easily lead a driver to believe that his or her use adequately compensates for degraded road conditions and that he or she no longer needs to reduce speed when roads become slippery. Unfortunately, such drivers are only *half* right at best. While the increased traction of their vehicles allows them to accelerate better on such surfaces, it does nothing to improve their ability to bring a vehicle to a stop, slow down, or turn. A driver in this case has altered his or her behavior in response to a *perceived*

increase in safety provided by an equipment change without understanding that the *actual* change in risk exposure does not correspond to the expected change.

This type of effect is not theoretical; an almost identical effect was found shortly after the introduction of anti-lock brakes (ABS). Two groups of drivers, one with ABS-equipped vehicles and one with standard brakes were compared. After a three-year familiarization and data collection period, a study found that the drivers using ABS-equipped vehicles actually were involved in *more* accidents than those without ABS. When more diagnostic performance metrics were examined, however, researchers learned the following about drivers in ABS-equipped vehicles:

They drove the ABS-equipped vehicles faster than individuals driving vehicles with standard brakes.

They made sharper turns in curves.

- They were less able to stay in their own lanes.
- They proceeded at a shorter forward sight distance.
- They made more poorly adjusted merging maneuvers.
- They drove the ABS-equipped vehicles faster than individuals driving vehicles with standard brakes.
- They created more "traffic conflicts," meaning situations in which one or more vehicles had to take swift action to avoid a collision.

Clearly, the ABS-equipped vehicles were operated differently than their counterparts without them. Equally clearly, these differences were the function of the behavioral changes on the part of the drivers, not the design changes to the brakes themselves. The individual "risk assessment" performed by the operators of the ABS-equipped vehicles was not based on a lack of information about the purpose, performance, operation, or use of anti-lock brakes, all of which they had been provided before the study began. ABS users misestimated the functionality of the product based on their successful initial experiences with of the system. (*I.e.*, "I've used the system in a particular manner without negative consequences so far; my behavior must therefore be safe.") Since there was no information regarding the brakes that the drivers did not *already* have, "warnings" could have accomplished little or nothing in this case. There were no problems with the design or operation of the ABS-equipped vehicles, so the "solution" to the problem did not lie in either redesign or guarding. The increased "hazard" of using ABS brakes stemmed entirely from the changed behavior of the operators; it was an unanticipated end result of an engineering change that produced a safer product, though ultimately not safer *use*. Parties in litigation, however, must ascertain whether or not an alleged failure to warn actually caused an accident in question.

Failure to Warn and Legal Causation

Under the Restatement (Second) of Torts, causation must be established by showing that had a proper warning been issued, behavior would have changed that would have prevented an accident and injuries. It is a plaintiff's burden to prove that he or she would have acted differently had an alleged proper warning or instruction been provided. *See In re Prempro Prods. Liability Litig.*, 586 F.3d 547, 565 (8th Cir. 2009); *Van Buskirk v. Carey Canadian Mines, Ltd.*, 760 F.2d 481, 492–93 (3d Cir. 1985); *Tracy v. Cottrell,* 524 S.E.2d 879 (W. Va. 1999).

The evidence on causation "must be such as to support a reasonable inference, rather than a guess, that the existence of an adequate warning" would have prevented the accident before the issue of causation may be submitted to the jury. *See Staymates v. ITT Holub Indus.,* 527 A.2d 140, 147 (Pa. Super. 1987) (underscoring supplied); *Powell v. J. T. Posey Co.*, 766 F.2d 131 (3d Cir. 1985); *Conti v. Ford Motors, Co.*, 743 F.2d 195, 198 (3d Cir. 1984). Hence, in *Overpack v. Chicago Pneumatic Tool Co.,* 634 F. Supp. 638 (E.D. Pa. 1986), *aff'd*, 823 F.2d 751(3d Cir. 1987), an alleged failure to warn or instruct was held not to be the proximate cause of the accident at issue because the plaintiff and his wife and coworker never received, attempted to obtain, or read the owner's product manual. *See also General Motors Corp. v. Saenz,* 873 S.W.2d 353, 361 (Tex. 1993).

In *Overpeck*, an alleged failure to warn or instruct was held not to be the proximate cause of the accident at issue because the plaintiff never received, attempted to obtain, or read the owner's product's manual. 634 F. Supp. at 641. Similarly, the U.S. Court of Appeals for the Fifth Circuit succinctly stated as follows in *Eyre v. McDonough Power Equipment, Inc.*, 755 F.2d 416 (5th Cir. 1985), when absolving a lawnmower manufacture from an alleged failure to warn of the machine's dangerous aspects: "[I]n logic we are unable to envision the causal significance of the adequacy or inadequacy of warnings when those that were given were not read; presumably the most adequate ones would likewise have been ignored." 755 F.2d at 418.

The operation of this principle is also tellingly illustrated in *Bloxom v. Bloxom*, 512 So. 2d 839 (La. 1987). There, the Louisiana Supreme Court affirmed the court of appeal's judgment in favor of the manufacturer despite concluding that the manufacturer provided inadequate warnings. Although the warnings were proved deficient, thereby entitling him to a presumption that a proper warning would have been read had it been given, the plaintiff failed to prove causation because he did not read the warnings that were provided. The Louisiana Supreme Court explained its holding as follows:

> [W]hen we examine the evidence, we find that the manufacturer has fulfilled not only its burden of producing contrary evidence but also its burden of persuading us that even an adequate warning in the owner's manual would have been futile in this case. Lonnie Bloxom testified on both direct and cross examination that he had not read any part of his owner's manual prior to the fire. He stated that it was not his practice to refer to an automobile operator's manual unless there was something wrong with the car.

Accordingly, even if an adequate warning of the particular danger in this case had been given by a proper provision in the manual, such a warning would have

been futile because Lonnie Bloxom did not read the manual before parking his car over combustible materials. *Bloxom*, 512 So. 2d at 850–51.

At the end of the day, if a party cannot show that he or she looked for, read, and relied on any supplied instructions and warnings, there exists no evidence that any different or other warnings or instructions would have been read and heeded and prevented the accident. Accordingly, the causation element would be severely damaged if not destroyed.

Conclusion

In an effort to reduce the potential risks from the improper operation or misuse of a product to an acceptable level, the choice of appropriate warning technology, and whether or not a warning, guard, or change to a product design is even warranted, should stem from analyzing the product, its operation, and its intended use. When warnings are warranted, the proper terminology and the method of presentation will depend on the nature, severity, and probability that an accident may occur. Even the best intended warning or instructions, however, will have no effect if the affected party never receives or never attempts to obtain or read a product's manual or warning/instructions. Specifically tailored and focused discovery, both written and in depositions, will assist in uncovering the necessary facts to defend against a failure-to-warn claim. If an affected individual does not receive, look at, or read what was provided, a defense attorney can argue persuasively that any alleged failure to warn did not cause an accident. FD