

## **Warnings and Instructions: Updated U.S. Standards and Global Requirements**

**By  
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The duty to warn is a subject that is of particular interest to me. I've counseled in the warnings area for over 30 years and have written extensively on the subject. Also, I am currently helping to assemble an updated global compendium on the duty to warn for DRI's Product Liability Committee which will be published probably early next year. As a result, I thought I would devote this column to a discussion of the duty to warn and some of the warnings standards that apply.

The ANSI Z535 set of standards dealing with product safety labels have been in existence since 1991. They have provided manufacturers with good guidance for the creation of safety labels and more recently, instruction manuals. Standards and legal directives in Europe dealing with safety labels are evolving. And there is an ongoing effort to harmonize the U.S. and European standards so that manufacturers can possibly sell their products with one set of safety labels around the world.

This article will discuss the new revisions to the U.S. labeling standards, some of the current ISO and EU requirements for warnings and instructions, and issues related to testing the comprehension of both warnings and instructions.

### **Basic Duty to Warn and Instruct**

The Restatement Third, Torts: Products Liability ("Restatement") makes it clear that product sellers must provide "reasonable warnings and instructions" about risks that exist in their products. *Restatement*, §2(c), *cmt. i.*

The Restatement differentiates warnings and instructions as follows. "Warnings alert users and consumers to the existence and nature of product risks so that they can prevent harm either by appropriate conduct during use or consumption or by choosing not to use or consume." *Restatement*, §2(c), *cmt. i.* Instructions

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“inform persons how to use and consume products safely.” *Restatement, §2(c), cmt. i.*

And, it has been held that warnings, standing alone, may have no practical relevance without instructions, *Antcliff v. State Employees Credit Union*, 414 Mich 624 (1982), and instructions without warnings may not be adequate.

Therefore, when the law talks about the “duty to warn,” it includes providing warnings on products in the form of safety labels, safety information in instructions, instructions that affirmatively describe how to use a product safely, and possibly even safety information in other means of communication such as videos, advertising, catalogs, websites, etc.

The law says that a manufacturer has a duty to warn where: (1) the product is dangerous; (2) the danger is or should be known by the manufacturer; (3) the danger is present when the product is used in the usual and expected manner; and (4) the danger is not obvious or well known to the user. *See Billiar v. Minnesota Mining and Manufacturing Co.*, 623 F.2d 240, 243 (2d Cir. 1980).

Once the decision has been made to warn, the manufacturer needs to determine whether the warning is adequate. Generally, the adequacy of a warning in a particular situation is a question of fact to be decided by the jury. However, there are a number of cases where the court has generally described an adequate warning. The United States Court of Appeals for the Fourth Circuit stated:

If warning of the danger is given and this warning is of a character reasonably calculated to bring home to the reasonably prudent person the nature and extent of the danger, it is sufficient to shift the risk of harm from the manufacturer to the user. To be of such character the warning must embody two characteristics: first, it must be in such form that it could reasonably be expected to catch the attention of the reasonably prudent man in the circumstances of its use; secondly, the content of the warning must be of such a nature as to be comprehensible to the average user and to convey a fair indication of the nature and extent of the danger to the mind of a reasonably prudent person. *Spruill v. Boyle-Midway, Inc.*, 308 F.2d 79, 85 (4th Cir., 1962) (Va. Law).

More specifically, various courts and commentators have described a list of requirements and goals of an adequate warning. An adequate warning will:

- Alert the consumer or user to the severity of the hazard; severity being defined as the magnitude of the hazard and the likelihood of it being encountered;
- Clearly state the nature of the hazard;
- Clearly state the consequences of the hazard; and
- Provide instructions on how to avoid the hazard.

The use of terms such as “reasonably be expected to catch the attention of the reasonably prudent user” and “characteristics of expected user groups” make it clear that, in the U.S., the jury gets to decide the adequacy of warnings. And, the reported trial court and appellate court cases have not been particularly helpful because there are so many variables in hazards, avoidance procedures, and the skills and backgrounds of the readers of the warnings.

On this point, the Restatement says:

In evaluating the adequacy of product warnings and instructions, courts must be sensitive to many factors. It is impossible to identify anything approaching a perfect level of detail that should be communicated in product disclosures. For example, educated or experienced product users and consumers may benefit from inclusion of more information about the full spectrum of product risks, whereas less-educated or unskilled users may benefit from more concise warnings and instructions stressing only the most crucial risks and safe-handling practices. \*\*\*\* Product warnings and instructions can rarely communicate all potentially relevant information, and the ability of a plaintiff to imagine a hypothetical better warning in the aftermath of an accident does not establish that the warning actually accompanying the product was inadequate. No easy guideline exists for courts to adopt in assessing the adequacy of product warnings and instructions. In making their assessments, courts must focus on various factors, such as content and comprehensibility, intensity of expression, and the characteristics of expected user groups.

*Restatement, §2(c), cmt. i.*

Case law concerning the adequacy of instructions is also not particularly illuminating. Most of the cases talk about the adequacy of warnings either on the

product or in the manual. In discussing the adequacy of instructions, the cases only say that manuals should be “adequate, accurate, and effective”, *Antcliff v. State Employees Credit Union*, 414 Mich 624 (1982), and “clear, complete, and adequately communicated”, *Broussard v. Houdaille Industries, Inc.*, 183 Ill App 3d 739 (1<sup>st</sup> Dist. 1989).

### **ANSI Z535.4 Standard on Labels**

For the last 20 years, the ANSI Z535 standards in the U.S. have provided guidelines on creating safety labels. Unfortunately, these standards mostly provide just formats for labels and instructions. As a result, it is possible to comply with these standards and still have inadequate content, thereby resulting in potentially legally inadequate warnings and instructions.

ANSI Z535 was initially published on June 6, 1991, with revisions in 1998, 2002, and 2006. The ANSI committee has just approved the 2011 revisions. This ANSI standard provides the basis for developing a safety label system. Unlike some other labeling standards, ANSI Z535.4 sets forth performance requirements for the design, application, use and placement of safety labels. The purpose of this standard is "to establish a uniform and consistent visual layout for safety signs and labels applied to a wide variety of products." It is also designed to create a "national uniform system for signs that communicate safety information."

ANSI Z535.4 deals with on-product safety labels and provides for a specific format label containing a signal word panel, word message panel, and an optional pictorial or symbol panel. The message required by the standard to be transmitted with words or symbols individually or in combination is (1) type of hazard, (2) the consequences of not avoiding the hazard and (3) how to avoid the hazard. These requirements are consistent with the case law that requires a label to convey the “nature and extent” of the danger.

ANSI Z535.4 was just revised and reaffirmed. The 2011 revisions include the following:

- Changes the definitions to make it clear that the emphasis for labeling is to communicate safety information to prevent injury or death and not just property damage.
- The signal word, CAUTION, is now to only be used for the risk of injury and not for the risk of property damage. NOTICE is the signal word to be used where the message relates to only the risk of property damage.

- There is a new “signal word” called SAFETY INSTRUCTIONS that can be used as a standalone sign or in combination with the typical safety label. This was allowed previously, but is now an official part of the standard. Other signal words, such as SAFE OPERATING PROCEDURES or SAFE INSTALLATION PROCEDURES, can also be used.

These revisions are fairly minimal as the standard evolves and would not necessitate any significant changes in current labeling. However, the upgrading of the SAFETY INSTRUCTION signal word gives a manufacturer more flexibility in including longer lists of safety precautions on the product. These lists could help accentuate the precautions in the manual and possibly even take the place of instructions that may or may not be near the product during use.

### **ANSI Z535.6 Standard on Instructions**

No matter what the manufacturer does to meet its “duty to warn” with on-product labels, with most products, it will need some instructions. Given the limited space on products, and the ever expanding need to warn about even remote risks, safety information in instructions is taking on increased importance.

A number of years ago, the ANSI committee concluded that while there are a number of other guides or standards that discuss instructions, there were none dealing specifically with incorporating safety information into instructions and how to interrelate these instructions with ANSI Z535 safety labels.

Therefore, it published a new part of the standard, ANSI Z535.6, to deal with this subject. This new standard was first published in 2006 and reaffirmed with minor changes in 2011. The standard:

“...sets forth a communication system developed specifically for product safety information in collateral materials. It incorporates elements of the graphical approaches used by other ANSI Z535-series standards into a common design direction selected to provide product safety information in an orderly and visually consistent manner.”

The standard provides requirements for the purpose, content, format, and location of four different kinds of safety messages:

- supplemental directives

- grouped safety messages
- section safety messages
- embedded safety messages

Supplemental directives direct readers to read the entire manual or to the safety information in the manual. They can be located on the cover of a manual or on the first page of a section in the manual. For example, while the standard doesn't specify any language, a boxed message on the cover should say something like "Read this manual before using this product. Failure to follow the instructions and safety precautions in this manual can result in serious injury or death." It should also say "Keep this manual in a safe location for future reference."

Grouped safety messages are commonly referred to as a "safety section." This section usually appears at the beginning of the manual, before or after the table of contents, and generally describes the risks involved in the use of the product and how to minimize or avoid them. These sections should include definitions of the signal words – Danger, Warning, and Caution – that are used on labels and in the manual, as well as reproductions of the labels in an illustration showing where they are attached to the product. If the product has symbol-only labels, the manual should describe the meaning of all symbols.

Section safety messages are included at the beginning of a chapter (i.e. maintenance or installation or operation) or within a chapter and do not specifically apply to a procedure. They include general messages such as "Do not perform maintenance without first reading this chapter and the safety precautions at the beginning of this manual" or "Failure to follow safety precautions in this chapter could result in serious injury or death."

Embedded safety messages are contained within a specific procedure. For example, "To prevent burns, wear protective gloves when performing this procedure."

These different kinds of messages have been in use for decades (a military standard from many years ago required a safety section in instruction manuals for products sold to the military), so many manufacturers' manuals will not change significantly.

Today, providing more interesting, compelling, and understandable safety information can be transmitted by video, CDs, and webcasts, in combination with written literature. Unfortunately, this standard does not provide any guidance on more effective ways to transmit safety information.

The challenge for manufacturers in the future will be to provide information in a way that is more likely to be read or viewed. While the law doesn't specifically require it, it is important for manufacturers to consider doing more to encourage people to read or view their instructions and to use their products more safely. The technology is certainly available. But how many manufacturers are fully utilizing it?

### **Testing Labels and Manuals for Comprehension**

The ANSI standard defines a safety symbol as a graphic representation intended to convey a safety message without the use of words. Z535.4 also states that symbols should be readily understood and effectively communicate the message. *ANSI Z535.4-2011, §11.1.*

In 2002, the ANSI standard was changed to allow the manufacturer to use a symbol to substitute for all or a portion of the required word messages "if it has been demonstrated to be satisfactorily comprehended ... or there is a means (e.g., instructions, training materials, manuals, etc.) to inform people of the symbol's meaning." *ANSI Z535.4-2011, §11.2.*

The original text of the ANSI standard did not allow a manufacturer to substitute a part of the message with a symbol unless the symbol had been tested to confirm that it was "satisfactorily comprehended." The 2002 change was meant to allow symbols to be placed on labels even if they haven't been tested as long as they were described in the manual.

However, while the ANSI standard now allows for symbols to take the place of words in the message panel, manufacturers understand that they should be careful before they rely on a symbol to fully communicate the message. Since symbols may represent a hazard, a hazardous situation, a precaution to avoid a hazard, the result of not avoiding a hazard, or any combination of these messages, it would be unusual for a symbol to be able to replace all word messages that are generally required by the law or the standard.

Manufacturers are able to use symbol only labels in the U.S. without running the risk of having a plaintiff's lawyer claim that their label violated the ANSI Z535 standard. However, the requirements in the law and in the ANSI standard for warning adequacy may not be satisfied with some symbol-only labels. In some cases, it may be very hard to create a symbol that portrays all of the message requirements.

Symbols are excellent at portraying the hazard and injury that can be suffered if encountering the hazard and, in some cases, not so good at portraying the severity of the injury, the probability that the injury will occur, and how to avoid the hazard.

Despite this, it is very possible that some symbols that do not transmit all of this information will be deemed legally sufficient without words because they provide enough information to put the reader on notice of a potential hazard and put the responsibility on the reader to get more information about the hazard's severity or probability and how to avoid it.

There are no legal requirements for a manufacturer to test its warnings or instructions for comprehension or effectiveness before they are used in the market place. While the case law talks about labels that are "comprehensible," that does not mean that they must have been officially tested to prove it.

The ANSI standard, Z535.4, and a related standard, Z535.3, discuss testing of symbols on labels for comprehension. In fact, in Annex B, which is not an official part of the standard, Z535.3 has a suggested procedure for evaluating new symbols. However, the ANSI committee is not testing or gathering tested symbols for general use by manufacturers.

But, there are inconsistencies in other standards on the issue of whether symbols must be tested. For example, in ASTM F1749 for fitness equipment labels, it says:

Pictorials may be used provided they have been tested in accordance with ANSI Z535 for user acceptance and understandability and give the user immediate recognition of the applicable hazard(s).

This requirement seems to require testing even if the pictorial is described in the instructions.

Since virtually all warnings contain words and some contain words and symbols, when a manufacturer is considering testing, it is important to consider when and if the symbol and words should be tested for comprehension.

Familiarity does not necessarily breed understanding and therefore it is possible that a symbol that has been used for many years by a number of manufacturers may still not be understandable. As a result, deciding whether a manufacturer



should rely on previously used labels will depend on that manufacturer's analysis of whether it is likely the label will be deemed legally adequate in the future.

In many cases, if a label has been in use for many years, and no claim has ever been made that the warnings or instructions are inadequate or unclear, then testing probably isn't necessary. However, the failure to test might violate the ANSI or ASTM standard applicable to the product.

Actual field experience can be used to show that the labels are understandable. However, in some situations, especially for new labels, that question might be answered by mere common sense and no testing or by a test among a very small group of foreseeable users. In some cases, a full blown study might need to be performed. This decision must be made by the manufacturer along with legal and communications professionals who can help analyze the necessity to test and the extent of the test if one is appropriate.

### **Foreign Labeling Standards and Directives**

The International Organization for Standardization (ISO) has a labeling standard, ISO 3864-2, that is very different from ANSI Z535. Symbols are the essential ingredient of this labeling system. Through the use of shape, colors, and symbols, ISO believes that each symbol can adequately communicate a safety message. As a result, the ISO standard has developed a wide-ranging system of symbols that are intended to portray the entire message.

Such a system is preferable in Europe because there are many languages spoken and read in different countries and there are open borders which allow products to easily move from country to country. The result can be that for many products, the manufacturer may not know where the product will be used during its lifetime. Having symbols that transmit at least part of the message provides some warning of the hazard.

However, there are some inconsistencies in approach to the use of symbols in the EU which are also different from those adopted in the ANSI standard. These differences could make it difficult for a manufacturer to comply with ANSI and EU requirements with one set of labels.

For example, the EU's Machinery Directive, effective December 2009, says:

Information and warnings on the machinery should preferably be provided in the form of readily understandable symbols or pictograms.

In June 2010, the EU issued a lengthy guide to the Machinery Directive. The commentary to the above section of the Directive said:

Well designed symbols or pictograms can be understood intuitively and avoid the need for the translation of written or verbal information.

I questioned the author of this Guide as to the meaning of the word “intuitively” and whether symbols had to be proven understandable or whether they could be explained in the manual and his response was that “...what makes a symbol or pictogram 'readily understandable' is its conventional use rather than the intrinsic characteristics of the symbol or pictogram itself or its resemblance to real objects or situations.

As mentioned above, the current ANSI Z535.4 says:

A symbol may only be used to substitute for a portion or all of a word message if it has been demonstrated to be satisfactorily comprehended (e.g., Annex B of ANSI Z535.3) or there is a means (e.g., instructions, training materials, manuals, etc.) to inform people of the symbol's meaning.

Therefore, even if the symbol has not been tested, it is acceptable if it is defined in the instructions.

When the inconsistency between ANSI Z535.4 and the Machinery Directive was pointed out to the author of the Guide, his response was:

I think the most important thing is to understand the very limited role of warnings marked on machinery according to the Machinery Directive. They may be useful to indicate hazards which operators or bystanders might ignore or forget and should therefore be understandable at a glance. For that purpose, unfamiliar pictograms that need to be explained in the instruction manual are not appropriate.

Therefore, for those utilizing pictorials on machinery to communicate part of the message in the U.S. and EU, they will have to determine whether pictorials need to be tested or not and whether they are readily understandable so as to comply with the Machinery Directive, ANSI Z535.4, and with the U.S. common law of warnings.

## **Conclusion**

Allegations of inadequate warnings and instructions are dangerous because it is so easy for a plaintiff to argue that the manufacturer should have done something different. If the label had words, then all they had to do is add a few more words and the accident would not have happened. If there are only symbols, then the plaintiff didn't understand it and all they had to do was test the label for comprehension. The remedy is cheap and simple and it may be hard to defend a particular label given a serious injury and sympathetic plaintiff.

There is a similar argument for instructions, either in the form of manuals that accompany the product or that exist on a website. The plaintiff couldn't understand the information, or it was inconsistent with the label and they became confused, or it didn't have certain information.

Manufacturers, with the assistance of counsel who are familiar with the law and practice in the area of warnings and instructions, should be sure to comply with any applicable standards that apply to safety communications. And, they should not do any testing without carefully analyzing whether such an effort is truly necessary and appropriate.

Manufacturers can certainly use symbol-only labels in the U.S. At least they will be able to say that the label complies with ANSI Z535. However, compliance with a voluntary standard is not an absolute defense. Therefore, they need to be prepared to prove how the symbol transmitted the required information.

As more and better warnings are placed on products and more safety information is created in manuals and elsewhere, plaintiff's experts will attack the adequacy of the labels on understandability and effectiveness. Every manufacturer needs to be prepared to rebut this argument by any available means.