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Danger! The Legal Duty to Warn and Instruct

by Kenneth Ross

A claim of failure to warn and instruct is a staple in product liability litigation. It is also a potentially dangerous claim because it is so easy to argue that adding a few words to the label or manual would have prevented the accident from happening. For example, a chemical manufacturer was held liable because use of the word "toxic" was deemed inadequate when the consequence of not avoiding the hazard was death. In addition, manufacturers have been held liable where their warnings were deemed not conspicuous enough, were placed in the wrong location or fell off of the product before the accident.

Standards for developing warning labels have been in existence for many years. However, in late 2006, the committee that created the warning label standards also created a new standard for instruction manuals. This committee, sponsored by the American National Standards Institute (ANSI), has created an excellent guide that should be considered by manufacturers as they evaluate their current labels and manuals.

This article will discuss the legal duty to warn and instruct, U.S. labeling standards, the new standard on instruction manuals and best practice suggestions.

Basic Legal Duty to Warn and Instruct

Product sellers must provide "reasonable warnings and instructions" about their products' risks. The law 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." Instructions "inform persons how to use and consume products safely."

A court has held that warnings, standing alone, may have no practical relevance without instructions and that instructions without warnings may not be adequate.

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

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.



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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, one court provided a useful description of an adequate label as follows:

"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."

More specifically, various courts and commentators 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
- provide instructions on how to avoid the hazard

A court must focus on a warning's "content and comprehensibility, intensity of expression and the characteristics of expected user groups" to determine its adequacy.

Case law concerning the adequacy of warnings and instructions is not particularly illuminating. Most of the cases talk about the adequacy of warnings either on the product or in the instruction manual. In discussing the adequacy of instructions, the cases only say that manuals should be "adequate, accurate and effective" and "clear, complete and adequately communicated."

Despite the lack of guidance from U.S. courts, there are voluntary consensus standards that do provide some help. The ANSI Z535 standards provide some good guidelines on creating warning labels and how to incorporate safety information into instructions. Unfortunately, these standards mostly provide format guidelines and not specific content guidelines. 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.

While compliance with standards is not an absolute defense, noncompliance can be used by plaintiff's experts to argue that the manufacturer did not keep up with the "state of the art."

ANSI Standard on Labels

ANSI Z535 was initially published on June 6, 1991, with revisions in 1998 and 2002, and another revision to be published this year. This ANSI standard provides the basis for developing a warning label system. Unlike some other labeling standards, ANSI Z535.4 sets forth performance requirements for the design, application, use and placement of warning labels for all consumer and industrial products.

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 the recognition of potential personal injury hazards for those persons using products."

ANSI Z535.4 deals with on-product warning labels and provides for a specific label format containing a signal word panel, word message panel, and an optional pictorial or symbol panel. It does not deal with instructions that accompany the product.

The message required by the standard to be transmitted, with words or symbols individually or in combination, is (1) nature of the hazard, (2) the

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seriousness of the hazard or probability that the user will encounter the hazard, (3) the consequences of encountering the hazard or the severity of the injury, and (4) 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 Standard on Instructions

Even if the manufacturer meets its "duty to warn" with on-product labels, with most products, it will also 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.

With some products, there is only room for one label referring the user to the instructions that need to be read before the product is used. Some courts have permitted manufacturers to do that and then place all of the specific safety information in the instruction manual.

ANSI Z535.6, the new standard dealing with instructions, was published in late 2006. The purpose of the new standard is, in part, to "establish a uniform and consistent visual layout for safety information in collateral materials for a wide variety of products and establish a national uniform system for the recognition of potential personal injury hazards for those persons using products."

The standard applies to all "collateral material" that accompanies a product but does not include safety information placed in advertising and promotional material, or stated in audio/visual material such as safety videos and websites.

The standard includes guidelines 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 does not specify any language, a boxed message on the cover should say something to the effect of: "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—such as "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, albeit without these fancy names, 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 may not change significantly. However, for the first time, the ANSI committee is giving guidance on how to locate and format the Z535-related information in the text of the manual. There is important guidance on formatting the safety information so it is easy to see but does not overwhelm the instructional text, as is common in many manuals.

This standard only dealt with basic safety instructions usually in a manual form. However, as technological capabilities continue to develop, the standards groups, including ANSI, will provide guidance on additional ways to transmit safety and instructional information.

Today, more interesting, compelling and understandable safety information can be transmitted by video, CDs and webcasts in combination with written literature. 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 does not 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.

What to Do

Every manufacturer of consumer products or industrial products should use the passage of this new section of ANSI Z535 to re-evaluate its warnings and instructions and other safety communications.

This is a complex area of law and practice. Other difficult issues that have not been discussed include the use of multilingual labels, use of pictorials in place of words, how to prove that the labels and instructions are understandable, whether to offer new labels and manuals to prior purchasers, and when to exceed the standards.

As a result, it would be a good idea for manufacturers to first ask legal counsel experienced in this area to perform a legal audit of their current warnings and instructions and provide a legal opinion as to what steps, if any, need to be taken to upgrade the current warnings and instructions. This legal audit and opinion can be done quickly in that counsel only needs to see one or two exemplar manuals that typify the kinds of warning literature the organization produces.

As an added benefit, the audit and opinion should be protected from disclosure under attorney client privilege. And, if assistance is needed by professionals such as technical writers and human factors experts, they can be retained by legal counsel and their suggestions can be provided to counsel and be considered by counsel in rendering a legal opinion. In that way, these suggestions would also arguably be privileged.

Be Prepared

As more and better warnings are placed on products and more safety information is inserted into manuals and elsewhere, plaintiff's experts will attack the adequacy of the labels if they do not comply with applicable standards. Every manufacturer needs to be prepared to prove that its safety communications complied with all legal requirements and applicable standards.

***Kenneth Ross**, of counsel to Bowman and Brooke LLP in Minneapolis, has provided legal advice to manufacturers on warning labels and instruction manuals since 1976. This article was adapted from a 2005 article authored by Ross and published by the Defense Research Institute.*