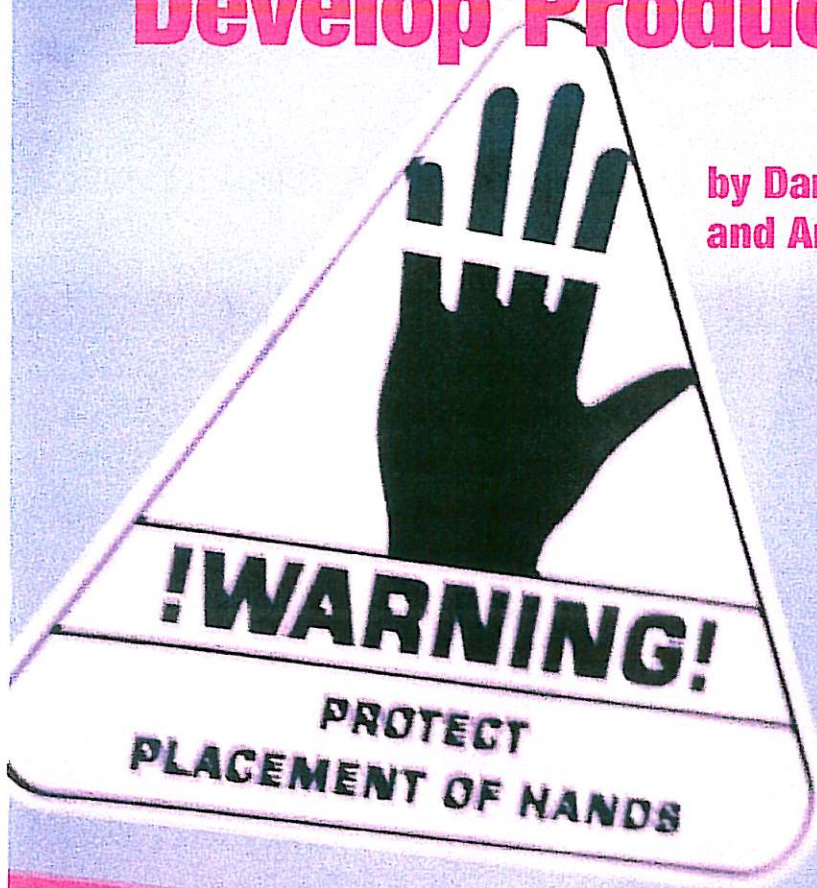


Guidelines for Practitioners

# Advising Clients on How to Develop Product Warnings

by Daniel P. Dain  
and Andrea L. Studley



Product manufacturers regularly ask counsel to play a role in the development of warnings to be placed on products, inserts, and packaging. In accepting such a role, lawyers should be mindful of the limits of their expertise in this area. Such limits may

require the lawyer to play more the role of coordinator or supervisor rather than active participant in the creation of the warnings themselves. Nevertheless, an understanding of the process through which warnings are created will assist the lawyer as counselor.



## Before You Get Started

There are two essential goals in creating product warnings: avoiding or minimizing injuries and preventing or reducing lawsuits. The lawyer as counselor should also be cognizant of an additional competing interest held by all manufacturing clients: to actually sell products. The trick is to create warnings that can help users avoid injuries and meet an industry standard of care, but do not scare potential users from wanting to buy the product in the first place.

The need to generate product warnings is dictated by state tort common law (or statutory law in some states such as Ohio and Connecticut). In general, a manufacturer has a duty to adequately warn of dangers of reasonably foreseeable uses and misuses of a product. The adequacy of warnings is judged, at least in part, by comparing them to the state of the art/industry standards. In most states, a manufacturer does not need to warn of open and obvious dangers or dangers within the common knowledge of the public or a trade or profession. Interstate commerce mandates that warnings should be designed so as to meet the lowest common denominator such that they can withstand scrutiny in any jurisdiction through which the product may pass.

## Part of a Process

The process of identifying hazards to be warned against and then creating the warning itself should, from the beginning, be an integral part of developing the product itself. Such a process should include:

- Organizing the team, including product engineers and designers, warnings consultants (such as those known as human

factor experts who can provide guidance on user expectations and behavior), and the salespeople who are most likely to interact with customers.

- Identifying hazards and considering whether the product can be designed so as to avoid the hazards altogether.
- Keeping updated on the state of the art/industry standards.
- Creating the warning. In doing so, have clear goals such as alerting the user of potential hazards, the consequences of those hazards, and how to avoid them.
- Testing the warning for effectiveness.
- Vetting the warning for factors that could undermine its efficacy.
- Documenting the process.
- Cataloguing feedback from users, such as safety complaints.

## Identify the Hazards (and Then Try to Avoid Them)

The warning development process must identify known or foreseeable hazards. This can be accomplished through:

- Product testing.
- Reports from the field/complaints from customers if product is already in use.
- Risks associated with comparable products.
- Common sense/brainstorming.

Once hazards are identified and understood, product warnings should be considered as a last resort. Keep these four points in mind:

- Eliminate hazards that can be eliminated.
- Reduce hazards that can be reduced.
- Guard against hazards that can be guarded against.
- If known or foreseeable hazards cannot be eliminated, reduced, or guarded against, they must be warned of. Any product warning label should identify the known or foreseeable hazards.

## Identify the Standard and Applicable Rules or Regulations

Any warning label must comply with appli-

cable regulations and meet the state of the art/industry standard.

The lawyer can take the lead in identifying applicable rules and regulations. For cigarettes, you should obviously consult the Surgeon General regulations. For drug and medical devices, you should review applicable Food and Drug Administration regulations. Other federal agencies provide specific rules that may apply to a particular product. Such agencies include the Consumer Products Safety Commission and the Environmental Protection Agency. Be mindful that some state regulations may be preempted by federal regulations. Failure to comply with applicable rules and regulations could create a presumption of negligence and at the very least be evidence of a failure to meet the standard of care.

Even in the absence of direct regulation, product warnings will be evaluated in comparison to the state of the art/industry standard. There are national and international organizations that act as depositories for the collection and maintenance of recognized standards. While compliance with these organizations' standards is considered voluntary, failure to meet them could be considered a failure to meet the standard of care.

In the United States, the leading organization is the American National Standards Institute ("ANSI"). The ANSI Z535 series provides detailed instructions on how to create a product warning and provides examples of standardized product-specific warnings. These can be purchased from ANSI. See <http://www.ansi.org/>. It may also be worth reviewing some standards developed before ANSI, such as the FMC Corporation Product Safety Sign and Label System (1985) and the Westinghouse Product Safety Label Handbook (1981).

A lawyer consulting on warnings for a product that will be sold or used internationally should review any applicable international standards. The principal source for these standards is the International Standards Organization (ISO), which describes itself as "a network of the national standards institutes of 148 countries." It is based in Geneva, Switzerland. Its website is at <http://www.iso.org/iso/en/ISOOnline.frontpage>. Note

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## Product Warnings, from page 11

that placing a product into the stream of international commerce can present particular challenges in crafting appropriate warning labels that will meet the standards for each country through which the product will pass. Since 1995, there have been efforts to harmonize the ISO and ANSI standards. Also keep in mind the language challenges for products in international commerce. This may indicate the need for greater reliance on pictorial warnings.

Beware of the easy shortcut of simply copying competitors' warning information. Do not assume that such warnings are compliant and have been adequately vetted and tested.

## Creating Warning Label Content

What follows are general guidelines based in part on the most recent ANSI Z535 series. They should not be a substitute for directly consulting the applicable rules and regulations and the state of the art/industry standard, nor should they replace assistance and cooperation from those with particularized expertise. Note that every warning label must be considered individually and must be evaluated in its own context.

In general, labels consist of three panels: a signal word panel, a message panel, and a symbol panel.

The *signal word* is meant to classify the relative seriousness of the hazard. It is generally written in all capital letters. The primary signal words are:

- **DANGER:** Use this signal word for the most extreme situations, where failure to avoid an imminent hazardous situation will result in death or serious injury to the person.
- **WARNING:** Use this signal word where a potentially hazardous situation could, if not avoided, result in death or serious injury to the person.
- **CAUTION:** Use this signal word where a potentially hazardous situation may, if not avoided, result in the risk of minor or moderate personal injury or where the potential hazard may result in property damage only.

The *message* is meant to identify three things using words: (1) the particular hazards, (2) the consequences of not avoiding the hazard, and (3) appropriate actions/avoidance behavior. The message should be concise and easily understood by the target audience. Here are some other considerations:

- Use headline style.
- Eliminate nonessential words, pronouns

(this, that, they), articles ( a, the, an), and forms of the verb "to be" (is, are, were).

- Use active voice: subject, action, object.
- Avoid prepositional phrases.
- Refer to another source, such as safety instruction labels, operation manual, operating procedures, safety bulletins, when necessary.
- Generally, hazard identification comes first, followed by the consequence and action/avoidance instructions. You can vary the order where the need to follow the action/avoidance message is immediate. For example: "Keep Out, Hazardous Voltage inside, 440 Volts."

The *symbol* is a graphic representation that conveys a message without using words. The symbol may represent a hazard, a hazardous situation, a precaution to avoid a hazard, a result of not avoiding, or any combination of these messages. At bottom, however, the goal is to create a symbol that is readily understood and effectively communicates the message.

There are four basic types of symbols:

- **Hazard alerting symbol:** This informs the user of the nature of the hazard. For example, a depiction of a hand placed near rollers could convey the risk of catching fingers in moving parts.
- **Mandatory action symbol:** This informs the user of actions that should be taken to avoid the hazard. For example, a depiction of a person wearing safety goggles could convey the message to wear safety goggles.
- **Information symbol:** This informs the user of general safety information, such as the location of exits or equipment. For example, a red cross could convey first aid.
- **Prohibition symbol:** This informs the user of actions that should not be taken. For example, a depiction of a fire with a slash across it could convey the message that there should not be any open flame near the product.

## Designing the Warning Label

There are extensive standards for how to format warning labels. The primary consideration is how to visually enhance the warning's message. In part, the goal is to make sure the warning label is readable from the minimum safe distance or, differently stated, the closest distance a person can be to the label and still have time to follow the message and avoid the hazard.

There are professional designers who specialize in creating warning labels. These designers will consider format issues such as:

- Should the information on the panel be arranged horizontally or vertically?
- If the message is being presented in multiple languages, how should they be arranged?
- If multiple hazards have been identified, how should they each be presented coherently?
- What contrasts should be emphasized to enhance distinctiveness?
- What colors should be used to make the warning most readable, and to reinforce the message and the seriousness of the hazard? Are there color combinations that may not be readable to users with certain color-deficiencies?
- In what style should the letters be presented?
- What size should the letters be?
- Should all-capital letters be used?
- What type spacing should be utilized?
- Is the amount of information being conveyed creating so much clutter as to undermine the effectiveness of the entire message?

## Vetting the Warning

Once the professionals have created and designed the warning, the lawyer should ask the following questions:

- Is the warning's content commensurate with the risk?
- Have the appropriate media or channels for presenting the warnings been chosen? For example, will the message appear only on the product itself or also on packaging, inserts, or websites? Should written warnings be supplemented by face-to-face instructions or training sessions?
- Are any aspects of the warnings inconsistent or at cross-purposes? Consistency across different channels is essential.
- Is the warning placed where the product users will see it?
  - Any warning must be reasonably calculated to actually place the user on notice of the hazards. A warning provided only on packaging that the manufacturer knows or can foresee will be discarded may not be sufficient;
  - Warnings on the websites and product literature should appear early on in case the user does not read the entire message; and
  - Warnings should be prominent, not buried in fine print or obscured by other information.
- Is the warning close to the known hazard?
  - *e.g.*, a warning about moving parts should be placed near those moving parts; and
  - *e.g.*, exercise equipment: a warning about

the risks of exercise should be placed where one actually engaging in the exercise can see it, such as handlebars on an exercise bike.

- Are there any environmental or setting considerations that could compromise or enhance the message's effectiveness? For example, a darkly colored label may be ill-advised if you anticipate that the product will be used in dimly lit areas.
- Is there anything about the intended recipient of the warning information that could compromise or enhance the message's effectiveness? For example, will people with limited reading skills use the product?
- Has the warning development process been properly documented?

### Testing the Warning

It is always advisable to test prototype warn-

ings on product users. Indeed, the fact that a warning was tested may itself be evidence of its reasonableness. You may want to consider engaging a consultant with expertise in testing product warnings. Typically such tests utilize focus groups and have objective pass/fail standards. The testing will help determine whether the warning is noticed by users, understood, and followed such that the hazard is avoided.

### Disclaimer of Warranties and Limitations on Damages

Issues separate from but closely related to safety warnings are warranty disclaimers and limitations on liability. These are beyond the scope of this article, but any product manufacturer should consider including them in product literature. The lawyer should review Uniform Commercial Code §§2-316 and 719.

Additionally, the lawyer should review all product literature for unintended warranties.

### Conclusion

Product manufacturers frequently ask both in-house and outside counsel to participate in the development of product warnings. Lawyers can play an integral part in this process by participating in the selection of the appropriate product warning development team, monitoring applicable rules and regulations and industry standards/state of the art, asking questions to vet the process, overseeing a testing program, and documenting everything. Through this role, lawyers can help their clients achieve the competing goals of protecting users, avoiding lawsuits, and keeping the product viable. **FD**



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