



Strictly Speaking

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Product Liability Prevention: How to create good product instructions and why is it so hard?

by Kenneth Ross



One of the most difficult tasks I perform in my product safety and prevention practice is to counsel companies on instruction manuals and other forms of safety communications. Unlike warnings attached to the product which should be short and to the point, separate instruction manuals and other forms of communication such as safety videos are unlimited in space and scope.

With instructions, space limitations are no excuse, and therefore, if a manufacturer forgets to include some pertinent instruction or says something unclearly, the plaintiff could easily argue that they misunderstood or were misled and suffered injury.

This article will examine the law, the standards and best practices concerning instructions and provide some suggestions on how to do a better job in the future.

The Law

The *Restatement 3d of Products Liability*, section 2, comment i, says that a manufacturer has a legal duty to provide both warnings and instructions. However, this comment distinguishes between instructions which are meant to "inform persons how to use and consume products safely" from warnings which "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."

When the *Restatement* discusses the adequacy of warnings and instructions, it uses the same criteria. It makes it clear that adequacy is to be judged by using a reasonableness test which it admits provides no easy guidelines. It encourages courts to focus on factors such as content and comprehensibility, intensity of expression, and the characteristics of expected user groups.

The common law is clear that instructions which do not warn of foreseeable hazards, but merely instruct as to how to use the product, are inadequate in meeting the duty to warn. In addition, courts have said that instructions must be "full, fair, and adequate," "adequate, accurate and effective" and "clear, complete and adequately communicated." This language is not very helpful in providing guidance as to what is reasonable.

The lack of guidance in the law and the difficulty in anticipating how a jury will react to a particular set of instructions makes the manufacturer's job somewhat daunting. However, there are some things that can be helpful.

Best Practices

There are many directives, guidelines, standards and checklists for creating instructions. The U.S. Consumer Product Safety Commission published a booklet in October 2003 entitled *Manufacturer's Guide to Developing Consumer Product Instructions* that is still one of the most comprehensive guides available.

This guide discusses preliminary matters such as planning the instructions for the intended audience and how to capture and maintain attention, how to make the text comprehensible, and how to motivate compliance. It provides some rules on how to present safety information and also on how to evaluate the instructions for



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Upcoming Seminar

comprehension.

A more recent document is ISO/IEC Guide 37:2012, entitled "*Instructions for use of products by consumers*," which gives recommendations on the design and formulation of instructions for use of products by consumers. It contains more detailed suggestions than the CPSC guide on format, words, illustrations, tables, flow charts, etc. This guide also has a checklist for the evaluation of instructions for use.

For machinery sold in Europe, manufacturers should consult the *Guide to Application of the Machinery Directive (June 2010)*, which contains many requirements and suggestions for instructions. The U.K. Department of Trade and Industry, in November 1998, published a very useful document entitled *Writing Safety Instructions for Consumer Products*, which surveyed consumers concerning their attitudes towards safety and reading instructions and included suggestions on how to encourage consumers to read instructions.

Lastly, for medical devices, the FDA published *Write It Right: Recommendations for Developing User Instruction Manuals for Medical Devices in Home Health Care* in 1993 which is still on the FDA website and still offers useful information on communicating to regular product users.

New Technology

There are some good company instruction manuals that you can see on the Internet that show what can be done with creativity and the use of technology: for example, see <http://www.toro.com> and <https://safety.cat.com>. Dr. Nathan Dorris described how technology can be used in *Twenty-First Century Warnings in a Global World: Another Tool in the Shed* that was presented at the 2013 Annual Meeting of DRI's Product Liability Committee. He discussed the Internet, video on demand, animation, dynamic displays and social media.

Another example of the use of technology is the use of QR codes (a square barcode) on a label on their product which takes the user to the instruction manual on the company's website when it has been scanned on a smartphone. This approach, combined with a warning telling the user to read the manual and telling them how to access the manual electronically if the hard copy manual is not available, will be helpful in arguing that you did the best you could to provide this information to the actual user.

ANSI Standards on Instructions

In 1991, the American National Standards Institute issued ANSI Z535 which dealt, in part, with on-product safety labels. This original standard did not provide any guidance on creating instructions that would accompany the product or any guidance on how to incorporate safety information into the instructions.

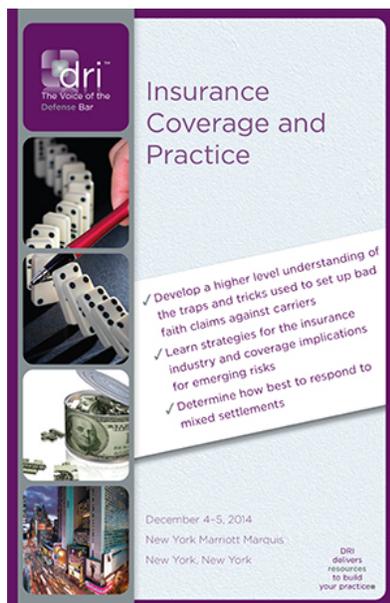
However, in 2006, the ANSI committee published a new part of the standard, ANSI Z535.6, to deal with the second part of the question, how to incorporate safety information that is contained in on-product labels into instructions. The standard says that it:

... 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 could 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



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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.”

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

[A few interesting issues](#)

There is very little guidance in the law or the general warnings standards on when safety messages can just be in the manual and not in the label? Or when they can be on the label and not in the manual? Some product-specific standards, including UL requirements, do specifically say whether the warning must be on a product or in the manual. Without a specific requirement, it is up to a manufacturer to decide.

The most logical analysis to me is whether the reader needs to see the information each time that he or she uses a product, or whether he or she can read the manual and then refer to that information later on as needed. Steve Hall from Applied Safety and Ergonomics and chair of the ANSI Z535.4 subcommittee said on this question:

There is no hard and fast rule, but generally you want to try to provide messages in a way that gives people a reasonable chance to read them at an appropriate time. So, for tasks that are expected to involve referring to the manual (e.g., assembly, troubleshooting, maintenance, etc.), it is generally reasonable to provide safety messages in the relevant part of the manual, and not on a label. Conversely, for scenarios where the target audience is not reasonably expected to have access to a manual, a label may be more appropriate.

In addition, Professor David Owen addressed this issue in his product liability treatise:

Whether adequacy requires in any given case that warnings be placed directly on the product involves a balance of the significance of the hazard, the user’s need for the information, the availability of a feasible means to place the warnings on the product, and other factors in the calculus of risk. If feasible, reason normally suggests that important warnings be placed on the product itself rather than in a pamphlet, booklet, or information sheet that can be damaged, lost, destroyed or stuffed in an office drawer.... Depending on the circumstances, however, a warning may still be adequate even if it is provided off the product in a manual or other writing.

Products Liability Law, pg. 601 (2d ed. Thomson West 2008).

For a more extensive discussion of this topic, see my article *Location of Warnings: On Product or in the Manual?* in *Strictly Speaking*, newsletter for the DRI Product Liability Committee, Summer 2008.

Another interesting issue involves whether the manufacturer needs to provide a hard copy of the instruction manual, or can you put the manual on a CD and

include it with the product or have a reference (website link or QR code) on the label to the manual on the company's website? The ANSI standards don't discuss whether a hard copy instruction manual is required, or whether the information can be provided in another way. The reason is most likely that most manufacturers provide their instructions in a hard copy.

However, there have been manufacturers of certain products that have recently asked about not providing a hard copy. Instead, they want to include the instructions as an electronic file in a product or in a CD format or just provide on a label a link to the manual on a website. Examples of such products would be cell phones, computers, TVs and certain machinery or equipment run by computers.

I have seen no law that discusses this issue and since, except as discussed below, virtually no laws or standards say one way or another, a manufacturer could omit the hard copy and argue that what it provided was adequate under the circumstances.

The ANSI Z535.6 subcommittee has been discussing the increased use of social media and company websites and how that relates to the required instructions.

However, for now, the ANSI Z535.6 standard does discuss the use of hard copies versus electronic instructions but merely mentions "supplemental directives," which could include references to website links, QR codes and other recognized types of safety messages.

In Europe, the *Guide to the EU Machinery Directive* specifically requires that a hard copy of the manual accompany machinery. Until the Guide changes, manufacturers of machinery have no other choice. However, in March 2012, the European Commission approved the use of electronic forms of instructions with certain medical devices intended for use exclusively by medical professionals. Manufacturers of active implantable medical devices, implantable medical devices, fixed installed medical devices and medical devices fitted with visual display systems will be able to provide in electronic form use instructions previously provided on paper. Manufacturers providing electronic instructions will be required to include notices on product packaging on how to access the electronic forms of instruction, or provide supplementary printed instructions on how to access electronic instructions.

In a few years, the standard practice concerning electronic versus hard copy instructions could be much different.

Why are good manuals so hard to create and what can you do about it?

We all read manuals at some time in our lives for products we buy and use. And we have all been frustrated trying to understand and follow some of the information we are relying on in these manuals. Why is that?

Manuals are very hard to write. It is very difficult to anticipate every question that a reader might have and to include every last step necessary to do something. Most of the time, the writer leaves out a crucial step, either because they forgot about it or because they thought it was obvious and they didn't need to include it. The more familiar the writer is with the product, the more likely they will skip over something that is obvious to them, but possibly not to a user. The answer, of course, is to have users review the manuals and try to understand them and help improve them where necessary. The CPSC Guide and ISO standard provide a protocol for testing the understandability of instructions with the CPSC Guide saying:

Your instructions should be evaluated and tested to confirm that the instructions are accurate and meet the goals you set forth when planning them. Conducting fully comprehensive "real world" assessments are difficult, but are necessary to understand what will happen when your instructions are in the hands of actual consumers.

In my experience, very little testing is undertaken, as it is very time consuming and potentially costly, depending on the length and complexity of the instructions. It may not be necessary to do actual testing; however, companies should consider ways to confirm at least the understandability of the critical information in the manuals. At a minimum, having manuals reviewed by experienced technical writers and maybe legal counsel experienced in safety will be helpful as such individuals are trained to identify unclear and incomplete statements and inadequacies in descriptions of safety precautions.

Another problem with manuals is in their organization. It is sometimes difficult to

organize a manual that flows in a logical fashion and starts from general to specific and includes information earlier that will be needed later. And, of course, most manuals aren't read in order. Specific sections are referred to as needed by the reader.

So, the manual, especially the safety information, needs to be cross-referenced from section to section and possibly repeated multiple times in different parts of the manual where it is appropriate. Figuring out how to do that can be very difficult.

Another problem is with the language. Most companies have manuals written by engineers, many who struggle with the English language on a daily basis. And even if they employ technical writers, these persons may not be familiar enough with the equipment and how it is to be used safely and properly to ensure that adequate safety information is included and stated correctly. So using technical writers with some technical background or who can interpret what the engineers are trying to say will go a long ways toward improving the understandability of the language.

Conclusion

Today, written literature can be combined with more interesting, compelling and understandable safety information that is transmitted by things such as video, CDs, webcasts, podcasts and YouTube. The challenge for manufacturers in the future will be to provide information in a way that is more likely to be read or viewed and understood and followed. Manufacturers should review the various guides, standards and requirements for writing instructions and decide what level of resources to devote to improving these safety communications. They should experiment with some of the new technology and evaluate the consumer's response.

Consumers don't read instructions because they are so boring or confusing or too long or incomplete. Breaking that cycle of inattention to this information will be helpful in enhancing the safe use of products.

Kenneth Ross is a former partner and now Of Counsel in the Minneapolis, Minnesota office of *Bowman and Brooke LLP* where he provides legal and practical advice to manufacturers and other product sellers in the area of design, warnings, instructions, safety communications, recalls and all areas of product safety and product liability prevention. Ken can be reached at 952-933-1195 or kenrossesq@comcast.net. Other articles on these subjects can be accessed at www.productliabilityprevention.com.

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