ANSI Z535.6 and product safety

Mistakes in manuals are far more common and can become more costly than design or manufacturing defects, warns Mathew Kundinger.

‘Product liability’ is one of those buzz words that scare manufacturers who want to market their products in the United States. It does not matter if the manufacturer is a domestic or a foreign company. The long arm of US courts is a threat for anybody who sells products in the United States.

News reports and articles concerning huge sums awarded by US juries in product liability law suits are everywhere. There has also been a lot of information published regarding the three legal theories that make up US product liability law:
- Breach of warranty
- Negligence
- Strict liability.

The following won’t address these three legal theories in detail, because anybody desiring clarification on the law can easily and quickly search on the Internet for ‘product liability’ and get a good overview in just ten minutes.

It is, however, noteworthy that most of the articles on product liability mention that the large majority of product liability lawsuits nowadays include allegations of failure to warn or other instructional defects in the manuals or in other collateral materials for the product, be it an industrial installation, power tools or a consumer product like a pushchair. The allegation of instructional defects is so commonly found in product liability complaints because basically all manuals have them, and many manuals are so poorly written that they are just a law suit waiting to happen. Those in the industry need to understand that lawyers are ready to pounce on unsuspecting manufacturers and exploit the many, often too glaring, defects to be found in written product materials.

Despite all the reports on the subject of product liability law, there is relatively little available on how manuals and collateral materials should be structured and what kind of detailed information they must contain to minimise the risk for manufacturers and to insulate them as much as possible against lawsuits based on failure to warn or instructional defects.

This article will examine from a multidisciplinary perspective the product liability dangers arising from poorly written manuals with missing, incorrect or insufficient warnings. It reflects my background as a German mechanical engineer who has been practising law in California since 1991, and whose pet peeve for about a quarter of a century has been having to read the incomprehensible instructions contained in many product manuals. I am a member of the American National Standards Institute’s ANSI Z35 committee (which deals with warnings and safety information) and ANSI Z535.6 subcommittee (which focuses in particular how warnings and safety information should be presented in manuals and other written materials).

The subject of warnings in product manuals is quite simple and yet seldom understood correctly and even more rarely implemented properly and sufficiently. The basic rules are:

1. If a hazard can be eliminated through an alternative design, it must be so eliminated.
2. If the hazard cannot be designed out of the product, it must be dealt with by covering the hazardous parts (like open chain drives) or by blocking access to the hazard.
3. If this route does not protect the user of the product from the hazard, the manufacturer must warn the user of the residual hazard. This means that sufficient warnings based on the latest standards must be given.

In other words, the warnings must be state-of-the-art. What this means for warnings in manuals and collateral materials has long been a subject of confusion and discussion. Until the ANSI standard Z535.6 was published on 10 October 2006, nobody really knew what warnings should look like. Technical communicators tended to improvise. They tried to adapt the ANSI Z535.4 standard, which sets forth how warnings on machines and many other products should look and what they should contain (Figure 1). We have all seen these types of warning labels on pushchairs, in cars or on washing machines.

While this was a logical approach to dealing with
the lack of any specific guidelines, it led to manuals being overloaded with huge warnings in block form which then trounced the text and made the manuals almost unreadable. Ten pages of warning block after warning block were not uncommon.

This, however, was certainly noticed by the ANSI Z535 committee. In response and because the ANSI Z535.4 standard was never intended nor designed to be used in manuals, a new sub-committee (ANSI Z535.6) was created to develop a standard for product safety information in product manuals, instructions and other collateral materials. On 10 October 2006, ANSI Z535.6 American National Standard For Product Safety Information in Product Manuals, Instructions, and Other Collateral Materials was published.

This standard now applies to all manuals and other collateral materials for products sold in the United States with the exception of those products for which specific standards already exist. One example of such products is prescription drugs, for which FDA guidelines exist.

Even though an ANSI standard is not law itself, and not binding like laws enacted by the legislatures on all levels (federal, state and municipal), it can be expected that ANSI Z535.6 will become the yardstick that is used to judge the sufficiency of warnings in manuals and collateral materials.

It is reasonable to expect this development since ANSI Z535.4, the American National Standard for Product Safety Signs and Labels that governs labels that are to be affixed to the actual products, has evolved into the standard that is used to judge the sufficiency of labels on products. The new ANSI Z535.6 standard may well reach the same status and be expected to be used in manuals, since it fills a void left by the lack of any standard that addresses warnings in manuals.

As a lawyer, I have to say that anybody who is involved in creating, designing or translating manuals or other collateral materials for products to be sold in the US must become familiar with and follow ANSI Z535.6 unless one of the few exceptions apply for the particular product in question.

The new standard, like other standards, sets only minimum requirements. Non-compliance with the standard will almost invariably lead to liability if this non-compliance can be causally connected to any injury or damage the plaintiff suffered. On the other hand, compliance is no guarantee at all for the sake of having uniformity in the entire document, because such uniformity helps to convey safety messages in a consistent fashion.

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In general, ANSI Z535.6 tries to follow ANSI Z535.4 and the other ANSI Z535 standards. It addresses written materials, be it manuals, pamphlets or other collateral materials including printable electronic documents such as PDF files. Its goals are to:

- Address the applicability of elements of the other ANSI Z535 standards to manuals and other collateral materials
- Establish a uniform and consistent layout for safety information
- Minimise the proliferation of differing designs for safety information
- Establish a national uniform system for the recognition of potential personal injury hazards
- Help manufacturers in providing safety information in their written materials
- Promote the efficient development of safety messages in manuals and other collateral materials

The new Z535.6 Standard acknowledges what I have been preaching for many years: continuity and uniformity. When, for example, Z535.6 would clash with other laws or regulations (like certain formats mandated by law to be used for warnings), then Z535.6 non-compliant warnings may also be used in the same document in places where no such direct clashes occur, just for the sake of having uniformity in the entire document, because such uniformity helps to convey safety messages in a consistent fashion.

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The ANSI Z535.6 definitions for the signal words follow ANSI Z535.4 (Figure 2). The rules of ANSI Z535.6 are at times very complex, but a few things are simple and clear:

- When the signal word DANGER is used, it has to be used with the safety alert symbol (triangle with exclamation point)
Implementation of ANSI Z535.6 in SCHEMA’s ST4 system

The software company SCHEMA, based in Germany, has now completely integrated ANSI Z535.6 into version 2.0 of its XML-based editing and content management system. SCHEMA ST4 is a standard software application designed for the efficient creation, organisation, and publication of all types of company product information. It contains interfaces to standard pre-press tools such as Adobe InDesign and Quark XPress, allowing quick and easy document production. Layout and content are separated, and product information is created as standardised text modules and stored in media-independent XML. Images and graphics are managed as individual modules as well, so that they can be reused at any time in new documents.

For the new version of SCHEMA ST4, the concept of safety instructions has been reworked and significantly expanded. On the one hand, it provides users in industries such as engineering and plant design with a powerful tool that contains safety messages conforming to ANSI Z535.6. On the other hand, it allows for more flexible design in other kinds of instructions such as software help systems. Version 2.0 also offers users the flexibility to design safety instructions to suit their own requirements. With the help of various dialog boxes, authorised editors or administrators can now specify safety instructions for all product information from a central location. They can set combinations of hazard level (such as instruction, warning or danger), type and source of danger (such as laser, heat and unspecified danger), warning symbol and other symbols (for example, showing protective measures such as wearing goggles or ear defenders). Visual elements, such as colour and border styles, can also be defined. During the editing process, users can insert predefined instruction sequences through the safety instructions menu. These facilities enable companies exporting to the US to protect themselves against liability arising from inadequate warnings and safety instructions.

- When the hazard can only lead to property damage but no personal injury or death, the safety alert symbol shall never be used. The signal words DANGER, WARNING, CAUTION and NOTICE shall only be used based on their definition. So, if someone wants to warn that a lid might pinch the fingers, DANGER is wrong and CAUTION should be used. Annex C4.2 on page 26 of ANSI Z535.6 has a useful flow chart that helps to select the correct signal words. In the past most people just guessed, which led to many wrong signal words in manuals. Now they can follow an easy to understand flow chart.

The standard divides the safety messages into four groups:
1. Supplemental directives
2. Grouped safety messages
3. Section safety messages
4. Embedded safety messages.

It gives guidelines, including how and when these messages should be used, how these safety messages should look and where the signal words or the safety alert symbol are to be located. A fifth group of messages covers property damage. These are by definition not safety messages, because they do not warn of personal injury hazards but only property damages.

ANSI Z535.6 mandates that all safety messages:
- Identify the hazard
- Give information on how to avoid the hazard
- Provide information about the likely consequences if the hazard is not avoided. This is in harmony with ANSI Z535.4.

While there is relief among technical communicators that there is finally a standard, their joy is limited. ANSI Z535.6 is very complex, not easy to understand and even harder to implement. Most technical communicators are somewhat lost unless they receive special instruction on the subject. It is also apparent, that many people do not understand that ANSI Z535.6 wants to eliminate the Z535.4 style warning blocks.

On the bright side, ANSI Z535.6 shows some attempts to harmonise with certain ISO standards, such as ISO 3864-1 and ISO 3864-2. It allows the yellow triangle with the exclamation mark (Figure 3) that is commonly used in Europe to be used with ANSI Z535.6 warnings.

It is clear that the push for harmonisation will continue and hopefully makes things easier and more uniform over the course of the coming years. Change will, however, only come slowly. People who expect a uniform standard that would be applicable worldwide or at least in the US and all over Europe will likely be disappointed. If at all, such a standard is at least fifteen to twenty years away.

The other challenge posed by the standard is the difficulty of automating the design of warnings. Technical communicators are looking for increasingly sophisticated software tools to streamline and automate the process of writing manuals and designing warnings.

Due to the huge variety of possible ways of designing warnings that are in compliance with ANSI Z535.6, only part of which make sense for any given application, the software developers still have some work to do. One of the programs currently available that implements important aspects of ANSI Z535.6 requirements is SCHEMA ST4, a standard software application which can be used to create, organise and produce product information efficiently.

But no matter how far this automation improves, technical communicators need to study the standard itself. There is no substitute for going to the source directly! The ANSI Z535.6 standard can be obtained from the same sources where companies and their staff obtain EU norms or it is available for download from www.global.ihs.com.

Conclusion
The long and short of the story is that missing or false warnings and instructional defects, if they can be linked causally to any injury or damage, can provide a much easier way for attorneys to make product liability claims, win a law suit or reach a settlement than proving an actual defect in a product.

With ANSI Z535.6 being available for close to two years now, it has become more important than ever for everybody involved with manuals and collateral materials to be aware of the mandates and to adhere to them or to get expert advice if they are unclear on any point.