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THE DUTY TO WARN

Do Warnings Make a Product Safe?

There have been several recent articles challenging the efficacy of warnings on products. One of the articles was published on the CNBC website on July 23, 2023, and is titled: "Warning labels in the U.S. seem to be everywhere. Here's why they may be pointless." This article was accompanied by a lengthy video commenting on this subject.[1]

The main points in the article are that people are desensitized to warning labels because they are everywhere. And warnings are the last solution to a safety hazard after design and guarding. Kip Viscusi, a law professor, said in the article that "There's a tendency to say things are risky [and] slap a warning on it, and that tends to dilute the impact of the other warnings that are out there."

While it is true that some manufacturers add warning labels when they should instead design their product more safely, most manufacturers must make difficult decisions knowing that not everyone reads and follows warnings.

The difficult question arises as to whether a manufacturer can make a safe product by fully relying on a warning or instruction that, if followed, would have prevented the accident. On that point, Bob Adler, the former Acting Chair of the U.S. Consumer Product Safety Commission (CPSC), observed that

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there are differences between a safe product and a product that can be defended in a product liability case. He said:

> *"…. [t]he law is clear: consumers' 'misuse' of a product may serve to defeat or diminish the recovery in a product liability lawsuit, but rarely does it provide a basis for invalidating a product safety rule.*
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> *"Product safety operates under different assumptions from product liability. Product liability affixes blame. Product safety fixes products. Product safety regulators look to whether an item can be made safe at minimal cost and inconvenience, regardless of a consumer's use or misuse of it."*[2]

Some members of the compliance staff at the CPSC believe that a product that hurts users when they don't follow warnings should be recalled. So, the question is whether a product that has been designed as safely as possible can be sold if the consumer must follow certain warnings and instructions to eliminate any hazards. The reality is that almost every product sold must be properly assembled, installed, used, and maintained for it to be safe and remain safe during its useful life. Thus, assuming that not all users will follow the warnings and instructions that help with safe use, one can only conclude that you can't sell a product where warnings and instructions must be followed. Thus, the only acceptable product is one that has been designed so safely that it can't hurt anyone. That is impossible and not a viable goal.

While adding an adequate warning to your product may result in a defense verdict in a product liability trial, it may not result in a safe product. Therefore, manufacturers need to consider what the law requires and whether it is acceptable from a safety standpoint to rely on a warning rather than designing out the hazard.

First, let's discuss the three kinds of defects and how the law describes the duty to warn.

DEFECTS

Product liability focuses on defects in products that exist at the time of sale. Over the years, there have been three clearly defined kinds of defects.

Manufacturing Defects

A manufacturing defect exists if the product "departs from its intended design even though all possible care was exercised in the preparation and marketing of the product." In other words, even if the manufacturer's quality control was the best in the world, the fact that the product departed from its intended design meant that it had a manufacturing defect. The plaintiff need not prove that the manufacturer was negligent, just that the product was defective. The focus is on the product, not on the conduct of the manufacturer.

Design Defects

There are usually only a handful of products that have manufacturing flaws. And it usually is proven that someone made a mistake or was negligent. It is different with design defects.

The manufacturer intended for the product to be designed and manufactured in a certain way. And the product turned out the way it was designed. The problem was that there was something deficient with the design.

A product is deemed to be defective in design if a foreseeable risk of harm posed by the product "could have been reduced or avoided by the adoption of a reasonable alternative design" and the failure to use this alternative design makes the product not reasonably safe. With this definition, a jury can rule that the product could have been and should have been made safer.

These tests are much more subjective than the test for manufacturing defects and this subjectivity is the cause of most of the problems in product liability today. Manufacturers cannot easily determine how safe is safe enough and cannot predict how a jury will judge their products based on these tests. It is up to the jury to decide whether the manufacturer was reasonable or should have made a safer product.

The law involving design defects includes the concept that it is better to design out the hazard than just warn or instruct about how to minimize or avoid the hazard. This is because warnings are less effective since people do not always follow them.

Therefore, the question is when you must design out the hazard and when can you rely on a warning that may or may not be effective.

Warnings and Instructions

The third main kind of defect involves inadequacies in warnings and instructions. The definition is similar to that of design defect and says that there is a defect if foreseeable risks of harm posed by the product "could have been reduced or avoided by …reasonable instructions or warnings" and this omission makes the product not reasonably safe.

Again, this is an extremely subjective test that uses negligence principles as a basis for a jury to decide. As with design, it is difficult for a manufacturer to know how far to go to warn and instruct about safety hazards that remain in the product.

Therefore, determining when there is a duty to warn or instruct, and how far that duty extends is one of the more difficult questions that needs to be answered by any manufacturer. The jury can easily conclude that an injured plaintiff would not want to be hurt or killed and, if the manufacturer had provided adequate warnings and instructions, the plaintiff would have followed them and not been hurt or killed. The fact that an accident occurred can mean, by definition, that it is possible that the warnings and instructions were inadequate.

This makes it easy for the plaintiff to argue that there was a defect in warnings and instructions and that the defect caused the injury. In such cases, it is also sometimes difficult for the manufacturer to explain why its warnings and instructions should not or could not have been better. And it is also easy for the plaintiff to argue that, since not everyone follows warnings, the design should have been safer.

DUTY TO WARN AND INSTRUCT

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.

Another way to state this is that there is a defect in the warnings when reasonably foreseeable risks of harm posed by the product could have been reduced or avoided by providing reasonable instructions or warnings, and that their omission renders the product not reasonably safe.

There is an interrelationship between adequate design and adequate warnings. For this article, we will assume that the manufacturer designed the product as safely as possible and that hazards remain. No matter how safe the design, most products have residual risks and need warnings, either affixed to the product or in the instructions.

Warnings alert users and consumers to the existence and nature of product risks. Instructions affirmatively inform people about how to use and consume products safely. Generally, warnings tend to be negative statements about things not to do or affirmative statements about things to always do. Instructions tend to describe in more detail how to do something safely and correctly.

The safety information on warning labels attached to the product can be a mix of affirmative, negative, or instructional information. The same is true for safety information in instructions that accompany the product. With this combination of information, users can minimize the risk of harm by following the warnings and instructions during use or by choosing not to use the product.

Warnings are usually contained in labels attached to the product or to the packaging or in hang tags that are attached to the product but are thrown away after purchase. Warnings can also be included in instructions that accompany the product and on a company's website and promotional literature.

DETERMINING RISK AND WHETHER TO WARN

During the design phase, manufacturers should do a risk assessment. This assessment identifies possible hazards with using the product and quantifies the probability that this hazard will occur and the severity of the harm that will be suffered if it occurs.

When this is completed and the product's design has been established, it should be relatively easy to identify residual risks which should require a warning. If the risk is not sufficient or not reasonably foreseeable, then a warning may not be necessary. There are no rules under the common law that tell a manufacturer when the risk is too small to warn about or when a risk is reasonably foreseeable. The jury gets to second guess the manufacturer's decision about whether to warn and about the content of the warning.

If the risk is obvious, a warning may not be needed. But this decision must be made carefully because the risk and the probability and severity of harm may not be obvious to some potential product users. Unfortunately, there are very few clear guidelines in this area. This is one reason why many manufacturers warn about many hazards including remote ones and obvious ones.

However, once a warning is created, the guidelines, standards, and law are a little more clear. But making this initial decision can be tough and one that should be done with legal counsel or a safety professional who is experienced in warnings.

ADEQUACY OF WARNINGS

Once the decision has been made to warn, the manufacturer needs to determine who to warn, how to warn, and whether the warning is adequate. The common law has said that a warning is legally adequate if:

- It is in a form that could reasonably be expected to catch the attention of a reasonably prudent person in the circumstances of the product's use;
- The content is of such a nature as to be comprehensible to the average user; and
- It conveys a fair indication of the nature and extent of the danger to the mind of a reasonably prudent person.

Despite this definition, terms such as "reasonable user," "fair indication," and "reasonably be expected to catch the attention of the user" make it clear that the jury gets to decide the adequacy of the warnings. Also, previously litigated cases are not particularly helpful because there are so many variables with each hazard, the avoidance procedures, and the experience of the readers of the warnings. Is the reader educated, uneducated, skilled, unskilled, or illiterate, or do they have poor reading skills?

On the positive side, there are U.S. standards (one of them is referred to as ANSI Z535.4) for designing warning labels that, if followed, will result in labels that look uniform. The ANSI standard requires that labels use a signal word – DANGER, WARNING, or CAUTION – and, in some cases, a pictorial or symbol, and then text. And, the text is supposed to describe the hazard, the probability of harm, the severity of the harm, and how to avoid the harm.

Beyond that, the ANSI standards do not tell a manufacturer how to determine if a warning is required and what language or picture to put on the label. For that, the manufacturer needs to make some important decisions. Again, because of the significant legal consequences that come from making a bad decision, consulting someone experienced with developing warnings is helpful.

A consultant may not be necessary if you are copying competitors' labels that appear to have been developed by competent people. But it is still a good idea for competent label specialists to review the labels to be sure they apply to your product and are likely to comply with applicable laws and standards and, if followed, would prevent incidents.

As Bob Adler said, a jury might believe that your warnings were adequate and rule in favor of the manufacturer. However, the product might result in accidents because people are not following the warnings. So, is the product safe? And does the manufacturer have a duty to inform the CPSC?

There are many examples of reports to the CPSC and recalls undertaken because accidents were occurring on products that had excellent warnings, but a small number of consumers were ignoring them and injuring themselves or others. Unfortunately,

a CPSC-sponsored recall of a product makes the defense of future litigation a bit more difficult. But, from a safety standpoint, it is hard to argue that a recall or other corrective action such as a safety education campaign is not appropriate if consumers are being injured or killed from ignoring the warnings or instructions.

OTHER CONSIDERATIONS

Difficult issues remain that must be decided by the manufacturer. Does a label have to be attached to the product or can the information be placed in the manual instead? How big should the label be? Where should it be placed? What kind of material should it be made of? How should it be attached? Should any language other than English be on the label? Should the warning on the label be repeated in the instructions?

The manufacturer must anticipate how it will defend itself by arguing that the information was clear and accessible, and that the user understood the importance of reading and following the warnings and instructions in the event the product becomes the target of a failure to warn claim.

There are no clear guidelines about what warnings should be placed on the product and which ones should be included in the instructions. The manufacturer must decide, based in part on whether it is necessary for the user to see the warning each time the product is used, or only once, or only periodically when the manual is read or referenced.

In addition, the location of the safety information in the manual is important to enhance the argument that the user must have seen the warnings given the placement and prominence of the information. Usually, manuals of some length include a safety section at the front where safety information and reproductions of the safety labels are included. This safety information may be repeated in the text of the manual in the location where the hazard exists. In short manuals, this section may not need to be included, and the safety information is just in the instructional text.

The manufacturer must consider how to get the manual to the user and make it accessible during the use or maintenance of the product. This cannot always be done and, many times, the warnings on the product will have to stand alone in providing critical safety information during use.

OTHER SAFETY COMMUNICATIONS

Many times, people do not read warnings and instructions until they are having problems with the product or until they hurt themselves. We cannot make people read safety communications. But one reason they do not read them is that they are not very interesting and are often difficult to understand.

So, when considering safety information, we should think about other ways to communicate in a more interesting and informative way. Instructional or safety videos, posters, and web-based interactive safety training may be important to supplement the written material. The technology is available to create such materials and the cost is not that significant. Manufacturers should consider going beyond written safety communications to adequately communicate the message.

CONCLUSION

This area of product liability law is dangerous because it is so easy for a plaintiff to argue that the manufacturer should have added a few more words and the accident would not have happened. As a result, creating new warnings and instructions (or updating your current warnings and instructions) should not be done without first obtaining assistance from legal counsel or other warnings consultants who know how to design and produce labels and manuals that comply with any applicable laws and standards and that are likely to be followed by most of the users.

Complying with the duty to warn and instruct in the United States and in foreign countries is not easy. The manufacturer must seriously undertake an effort to do so, both for the safety of the product and to enhance the ability to sell the product both here and abroad.

ENDNOTES

1. https://www.cnbc.com/2023/07/23/why-most-consumers-ignore-warning-labels.html
2. Robert S. Adler, "Reflections of an Unapologetic Safety Regulator," *The Regulatory Review*, October 17, 2022.