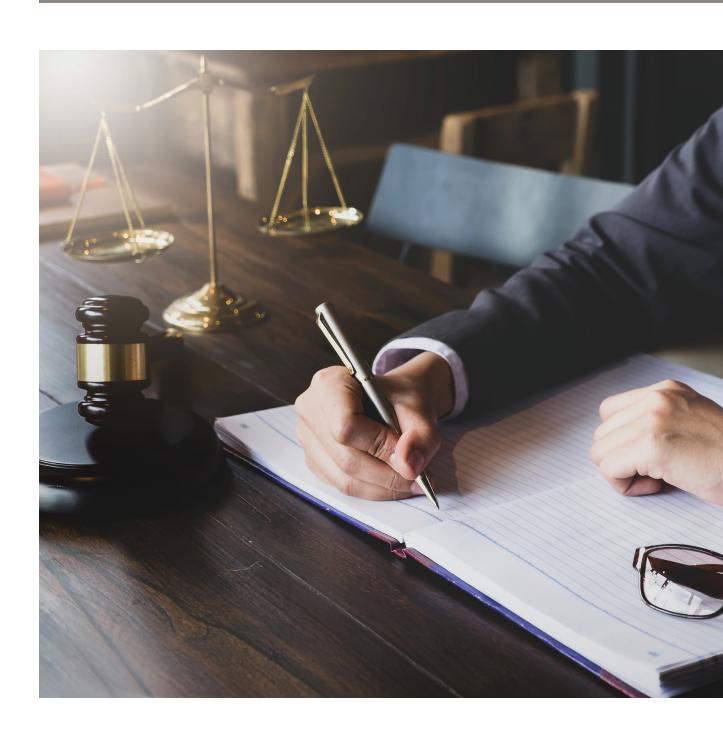
THE EFFECT OF STANDARDS ON SAFETY AND PRODUCT LIABILITY LITIGATION

Using Standards to Defend the Product



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By Kenneth Ross

Product liability has created problems for manufacturers and product sellers for many decades. These problems have been exacerbated by the expansion of product liability laws throughout the world. In addition, there has been a proliferation of safety regulatory requirements, starting in the United States (U.S.) and then moving to the European Union. In addition, countries such as Japan, China, Australia, Canada, Brazil, and South Africa have all recently established or strengthened their product safety regulatory regimes and requirements.

This all creates additional challenges for manufacturers who want to comply with all laws, regulations, and standards in any country where they sell their products. Such companies may also need to consider safety requirements in countries where they do not sell products if they believe that these requirements establish a floor for safety that they want to meet.

This article will discuss the basic kinds of defects that can be alleged in any product liability case, the law as it pertains to compliance with standards, and some tips on how to deal with the issue of standards compliance.

U.S. THEORIES OF LIABILITY

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, if the product or any of its components departed from its intended design, it most likely had a manufacturing defect. The plaintiff need not prove that the manufacturer was negligent, just that the product was defective and that the defect caused harm. The focus is on the product, not on the conduct of the manufacturer.

Common examples of manufacturing defects are products that are physically flawed, damaged, or incorrectly assembled, or that do not comply with the manufacturer's design specifications. The product turned out differently from that intended by the manufacturer. If that difference caused injury, the manufacturer is likely to be held liable and there are very few defenses.

Design Defects

A product is defective in design if a foreseeable risk of harm posed by the product or a component "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. An alternative definition used by some courts is that a product is defective in design if it is dangerous to an extent beyond that which would be contemplated by the ordinary consumer.

These tests are much more subjective than the test for manufacturing defects and this subjectivity is the cause of many of the problems in product liability today. Manufacturers cannot easily determine how safe is safe enough and cannot predict how a jury will judge whether they were reasonable or whether they should have made a safer product.

Warnings and Instructions

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



There are two kinds of design defect cases, those involving "inadvertent design errors," and others involving "conscious design choices."

Again, this is a subjective test that makes it difficult for a manufacturer to know how far to go to warn and instruct about safety hazards that remain in the product.

LAW OF DESIGN DEFECTS

There are two kinds of design defect cases, those involving "inadvertent design errors," and others involving "conscious design choices." Design errors are like manufacturing flaws and are easily treated by the courts. The design was wrong because someone made a mistake. The mistake created a hazard, and someone was hurt. In that case, there is virtually no defense, and the manufacturer would usually settle the case.

The more important type of design defect involves conscious design choices. In these cases, the design turned out as intended by the designer and manufacturer. It had the level of safety expected by the designer for the intended use. However, the product still hurt someone who claims that the product should have been made safer. The plaintiff argues that an alternative safer design should have been used and the court must decide whether this alternative was preferable.

The development of the law in this area has caused confusion. There are several tests that have been developed for helping courts and juries decide whether there was a defective design.

Testing for Design Defect

As previously mentioned, the predominant test in the United States for determining whether a product was "reasonably safe" involves whether there was a reasonable alternative design available. In many states, to answer this question, the jury is instructed to consider the following factors:

- Usefulness and desirability of the product
- Safety of the product, that is, the likelihood that it will
 cause injury and the probable seriousness of the injury
- The availability of a substitute product that performed the same function and was safer

- Ability of the manufacturer to eliminate the unsafe characteristic of the product without lessening its usefulness or making it too expensive
- User's ability to avoid harm by being careful when using the product
- User's awareness of the risk, either because it is obvious or because of suitable warnings and instructions
- Feasibility by the manufacturer to spread the risk by way of price increases or purchasing insurance

These factors provide a more comprehensive and understandable basis for a jury to make a decision. They also provide more guidance to the litigants to evaluate their case. And, as importantly, they provide a basis by which a manufacturer can evaluate the safety of its product before sale and decide whether it is "reasonably safe."

Compliance With Laws, Regulations, And Standards

Another way that a manufacturer decides that its product is safe enough is if it complies with laws, regulations, or standards. In fact, many engineers believe that such compliance is sufficient by itself. As will be discussed, some of the time, that is not correct or at least is questionable.

Laws and regulations are always mandatory, and standards can be mandatory or voluntary. As part of the initial analysis, a manufacturer must identify those that apply to its product. Sometimes, that is not easy to determine or there are numerous and conflicting ones that must be reconciled, especially if the product is sold internationally.

Compliance with official laws and regulations that apply to the product's design, such as those passed by a state or federal legislature or standards that have been adopted by a governmental agency, is mandatory. If the product does not comply and this noncompliance caused injury, the manufacturer can be liable. Unfortunately, on the flip side, compliance with all

applicable laws, regulations, and mandatory standards is not, for most products, an absolute defense in a product liability case. Therefore, a jury could come back and say a manufacturer should have exceeded laws and regulations pertaining to safety.

Industry standards, which are normally voluntary unless adopted by a governmental agency, including certifications issued by UL, ETL, or others, are considered by the law to be minimum not maximum requirements. As a result, compliance with voluntary standards and certifications is also not an absolute defense although it might be helpful to prove that the product was reasonably safe if this evidence is allowed to be presented to the jury.

As with laws and regulations, noncompliance is a problem if it caused or contributed to the injury. The reason is that the standard establishes a reasonable alternative design, and the manufacturer has to justify why it didn't comply. In addition, the plaintiff can also argue that mere compliance resulted in a defective product and that a manufacturer should have exceeded the standards.

DOES COMPLIANCE EQUAL SAFETY?

An analysis of recalls of consumer products undertaken between 2016 and 2020 showed that the vast majority of recalls were based on an unsafe product and not a non-compliant one. Therefore, while compliance is important, it does not guarantee safety. So, while the manufacturer must meet or exceed laws, regulations, and all applicable safety standards, determining when to exceed a standard requires a complex analysis that will always be criticized if there are accidents and there is an alternative design that would make the product safer.

But many times standards are not the answer or are not that helpful. Here are a few reasons:

- The vast majority of products do not have mandatory safety standards that are applicable to the product. Out of about 15,000 products overseen by the U.S. Consumer Product Safety Commission (CPSC), the CPSC has only issued or adopted about 70 mandatory standards.
- Where a standard applies, it may not apply to the entire product. So, for example, UL standards mostly deal with the electrical part of a product

- and maybe nothing else. So, a UL certification will be good evidence that the electronics are at least compliant with a UL standard, but it does not guarantee that other parts of the product are safe.
- Many standards are performance standards but allow the manufacturer to design it any way they want. And the standard may allow a manufacturer to use one of several acceptable safety features. This allows the plaintiff to argue that the safety feature selected was not the best choice and that another alternative would have been better.
- Standards are sometimes not clear and are subject to interpretation.
- There are overlapping standards and inconsistent standards from country to country.
- Some standards are not really requirements, but merely guidance on how to do something. For example, the ANSI Z535.4 standard on warning

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In the U.S., compliance with safety standards adopted by the CPSC is mandatory. If you don't, you must report the non-compliance to the CPSC and may have to recall the product.

labels is very flexible and allows for exceptions. It is also a design standard; therefore, it is possible to comply with the Z535.4 design and have legally inadequate content. On the other hand, there are other labeling standards and laws that provide for specific required language for certain hazards, but these requirements may also be deemed inadequate.¹

- Some standards have very specific requirements that are a bare minimum, and the manufacturer is prevented from exceeding the standard while still being able to claim that they complied with the standard's requirements. The result is that they are required to manufacture a potentially defective product so they can say they are compliant.
- And many standards are just made up without any technical or scientific analysis or testing on whether the requirements are likely to result in a safe product. They are merely educated guesses.

In the U.S., compliance with safety standards adopted by the CPSC is mandatory. If you don't, you must report the non-compliance to the CPSC and may have to recall the product. And where mandatory standards have been adopted, the manufacturer usually must retain an independent third-party testing laboratory and obtain confirmation that the product complies. If the product doesn't comply, the manufacturer must then decide whether to have another laboratory test the product and, if it does and the product complies, be required to explain the inconsistent test results.

With some products, the CPSC testing laboratory itself will conduct testing to confirm compliance. If their testing produces a different result from that of the third-party testing laboratory, the CPSC test results will prevail, and you may have to recall your product because of this non-compliance.

Organizations like Consumer Reports (CR) also test products to their own standards, which may differ from comparable voluntary standards or CPSC-mandated standards. So, it is possible that the manufacturer will obtain a third-party laboratory test result confirming compliance and then CR tests the product and concludes that it is unsafe because it doesn't comply with CR's testing protocol. In such a case, which test result takes precedence, and what do you do about this non-compliance? The manufacturer has to deal with this inconsistency from a safety and a marketing standpoint.

DOES COMPLIANCE PROVIDE AN ABSOLUTE DEFENSE TO LITIGATION?

Unless the specific law includes a provision saying that compliance will prevent any injured party from suing for product liability, manufacturers of compliant products can still be sued. There are virtually no laws that include such a limitation and governmental regulations and mandatory and voluntary standards would rarely, if ever, have such a limitation.

So, let's assume that you comply and have a testing laboratory confirm compliance. Do you have a problem? With some allegations, such as strict liability, conduct is not relevant and therefore compliance with standards would not usually be admissible. Where negligence is alleged, evidence of the manufacturer's conduct can be placed into evidence. But, in that case, the plaintiff can still argue that the standard was minimum and that you and your competitors could and should have made a safer product that would have prevented the accident.

If your competitors make a safer product by exceeding the standard and you don't, then you could also have a problem. You would need to explain why your less safe product is safe enough,² and why you didn't comply with the state of the art.

WHAT TO DO?

CR had an interesting special report on testing of products for safety and gaps in the system.³ It cited a 2020 survey it conducted that said that 96% of Americans believe that the products they buy for their home comply with a required safety standard and that

97% of respondents expect manufacturers to have tested their products for safety before selling them.

However, unless the product has a certification mark or logo on the product itself, consumers will not know what products have been tested and whether they comply with safety standards. Of course, consumers will also not know if the standard is adequate or is the bare minimum, or whether the standard applies to all aspects of a product that contribute to or detract from safety.

In the past, there have been a number of observers who believe that meeting or exceeding the requirements of standards is done mostly for marketing. The CR study results above confirm that. In addition, if a manufacturer wishes to work with a retailer that insists that the product be certified by an independent third-party, the manufacturer will need to do so, even if they are confident that the product is safe and does not require further testing.

Despite all of these limitations on the effectiveness of standards and the ability to defend the product, it is imperative that you comply and make a reasonable judgment as to when you need to retain a testing laboratory to test your product, or whether you can conduct testing yourself. In all cases, you need to document what you did to select the applicable standards, how you confirmed product compliance, and, if the product is not compliant, why you still believe that it is reasonably safe.

On the question of when to exceed standards, that is a big unknown. Even if there are standards to consider, the manufacturer should undertake a risk assessment so that they can determine if the standards are adequate to reasonably assure a safe product, or whether exceeding the standards' requirements is needed. Certainly, if comparable products produced by competitors exceed the requirements of a given standard, then you need to do so unless you have good proof that a less safe design is safe enough.

In addition, if you sell a safer product outside the U.S. because of more stringent standards in that country, then you need to decide whether you should also sell that safer product in the U.S. Safer products sold elsewhere are evidence of a safer alternative design and can create admissible evidence by the plaintiff's expert that you could have sold that foreign version in the U.S.

CONCLUSION

Product liability in the U.S. is based, in large part, on the plaintiff offering a safer design and arguing that the manufacturer should have sold this safer product. While standards are important, compliance with them does not necessarily result in a safe product. Manufacturers have the difficult task of deciding how safe is safe enough while also trying to meet the standards that are common in the marketplace for their products and how to not add unnecessary safety that puts the manufacturer at a competitive disadvantage. ©

ENDNOTES

- 1. ANSI Z400.1/Z129.1-2010 and Federal Hazardous Substances Act
- 2. See "The Risks of Optional Safety," *In Compliance Magazine*, May 2021.
- 3. Consumer Reports, June 2021, page 44.

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