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## Product Liability Risk Management

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Headlines in the news virtually every day trumpet some new problem with a product that has caused accidents, quality problems, consumer dissatisfaction, recalls, and government fines and resulted in product liability lawsuits, shareholder litigation, class actions, Congressional inquiries, and the like. The risk of product liability is much higher today as the news media is more likely to highlight these stories; consumers, consumer groups, and government agencies around the world are more likely to see these stories and take action; and some plaintiff's lawyers are willing to instantaneously bring claims based on virtually any problem, big or small.

American product liability laws and governmental safety regulatory schemes have been successfully exported to many countries around the world. These countries have adopted some form of product liability law allowing for suits based on defective products. And, many governments have adopted or enhanced product safety regulatory laws which increase the manufacturer's responsibility to report safety problems to the government and possibly undertake some post-sale corrective action such as a recall. Just this year, countries such as Australia, South Africa, and Canada have enacted or are considering enacting such laws.

In addition, there are more developments involving product safety management. Recently, as part of a settlement of a civil penalty case, the Consumer Product Safety Commission required a company to establish a fairly comprehensive safety management program. And next year, the biggest retailers in the world are rolling out new safety management requirements that companies that sell to them must comply with. These include independent audits confirming compliance.

These developments should alarm manufacturers and others in the supply chain and cause them to focus more than they have in the past on managing legal and business risks. And lawyers should become more knowledgeable about how to provide useful advice to companies so as to meet their business goals and decide on an acceptable level of risk.

Helping manufacturers and product sellers prevent or minimize the risk of such legal problems is called "product liability prevention" or "product liability risk management" (referred to in this article as "risk management"). These concepts are more than "legal compliance" in that one can comply with the law and still have legal problems. And they also do not stop at compliance with a company's business ethics policy. A company can be ethical and still have legal and business problems. The key is to identify and quantify potential legal problems and prevent or minimize the risk of their occurring and also to be prepared to deal with them if they occur.

Risk management is both proactive and reactive. It can be done before an event, a transaction, or the sale of a product and includes planning for litigation before it occurs. Or, it can take place after a legal



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problem arises and includes the defense of litigation and trying to prevent the problem from occurring again in the future.

Over the years, it has been difficult to get manufacturers interested in hiring or using lawyers to help them prevent legal problems that have not yet occurred, especially as they pertain to product liability. Most business people think of hiring a lawyer after a legal problem occurs. Fortunately, when I first became an in-house lawyer in the late 1970s, I was asked to help my businesses prevent accidents, thereby minimizing the risk of future product liability litigation. I fell in love with this part of my practice and have devoted most of my legal career to risk management, even after I left a corporation and went into private practice.

Lawyers, even those trained in the benefits of providing risk management services to their clients, especially in product liability, seem reluctant to offer this advice. One reason is because it is perceived to be very speculative and not directly based on case law, regulatory law, or even transactions. In contrast, after an incident has taken place and a legal problem arises, there are facts concerning the incident, a place, a time, and known parties. When advising on risk management before the event has taken place, none of that is known.

With product liability risk management, clients are asking the lawyer to help them comply with the common law and regulatory law where nothing has yet happened—and to do so in all 50 states and around the world for as long as their product is in customers' hands. If something happens, they want to be protected. Giving legal advice in that situation is challenging and sometimes scary.

So let's examine some of the areas in which lawyers should be involved in providing advice on product liability risk management and how such advice can be given.

### **Predicting the Future**

Predicting future legal problems involves risk assessment and is a necessary ingredient to successfully advising on risk management issues. It involves an identification of potential legal and possibly nonlegal problems that could occur and then a quantification of both the probability of occurrence and consequences (severity) if they do occur.

But, you can't just assume a "worst case scenario," assuming high probability of the worst outcome. If you did, your clients would, if they followed your advice, do many things that probably aren't necessary. You have to be practical, but be sure the client understands the risks of doing or not doing certain things.

So, what do you do? Where do you draw the line? Where should your clients draw the line? How do you estimate probability? This is the hard part of preventive lawyering. While we need to know the common law generally, since we don't know where the legal problems may arise, it is not that useful to consider the law in specific jurisdictions. Basically, the jury will tell the manufacturer if it complied with the common law after the incident occurs. Before the incident, we just have to make an educated guess as to what the law might be and how the jury might react to a certain product.

We also need to know the applicable regulatory law, but that is only the start to giving advice in this area. Such law is also usually vague, subject to interpretation, and how the applicable government agency will interpret the law and when the agency will enforce it may also be unclear. Enforcement comes and goes, usually with a change in political parties, and it is difficult to know how much weight to give to that issue in assessing risk at any point in time. And, of course, lawyers should not advise their clients to violate the law even if the law is not being enforced.

Lawyers can play a crucial role in helping clients identify risk and then giving them legal advice on what could happen if it isn't avoided and what procedures can be taken to avoid it. And, in fact, we should also not be shy about putting on our business hat and telling clients whether what they are going to do is a good or bad idea, even if it complies with "the law."

The reality is that whatever the client does, if there is an accident, there will be someone who will come up with something else the client could have done which would have prevented the accident. It is this 20/20 hindsight that makes it difficult to know how far to push the client. Perhaps the manufacturer who follows the detailed advice of plaintiff's and defense counsel fully would find it impossible to actually come up with a product that can be easily used and is not too expensive.

## **Risk Management Techniques**

The goals of any risk management program are (1) minimize the potential for product-related incidents; (2) comply with the common law and government regulations; (3) provide a good defense if an incident or non-compliance occurs; and (4) evaluate incidents or non-compliant products and try to prevent future problems from occurring. It is clear that the process is circular and never ends.

## **Personnel**

Training all relevant personnel in product liability, regulatory law, and product safety can help integrate risk management activities into everyone's job. Even if not directly involved in managing risk, all employees can benefit from a basic knowledge of product liability and regulatory law and the practices and policies of their employer and other companies so they can recognize when to raise issues and consult with others.

Widespread training also allows the company to avoid having to employ full-time personnel to manage risk and encourages everyone to take ownership and responsibility for such matters within their organizations. In this model, any full-time inside or outside risk management personnel basically function as a resource to answer questions or obtain answers from outside resources.

## **Getting Started**

The first step in a risk management program might be to perform a legal and safety risk assessment. Identifying and analyzing problems that have occurred or could reasonably occur will help focus the program on real problems, not make-believe problems that may never occur or result in any significant potential liability.

How do you predict the probability of something happening in the future, especially if it hasn't happened before? It is hard to do and requires judgment. But at a minimum, a risk management lawyer can research claims and litigation involving similar products or similar manufacturers to identify and quantify likely risks.

Documenting the risk assessment process is critical because it represents the manufacturer's thinking as to potential problems. Not all risks have to be minimized or prevented. Where to draw the line is a legal, technical, business, and ethical question. What is most important is that the risk management lawyer help the manufacturer identify, gather, evaluate, and synthesize all of the relevant information, make a rational decision, and properly document it.

While this analysis may not accurately predict future risk, it should confirm the manufacturer's commitment to try to minimize or prevent risks and document the basis of the prediction. As actual field experience with the product comes to the manufacturer's attention, this analysis may change, thereby necessitating a future design change or even a corrective action.

## **Manufacturing Defects**

To prevent manufacturing defects, manufacturers, at a minimum, need to ensure that their products have been manufactured and assembled according to all design and manufacturing specifications and that those specifications comply with all relevant voluntary or mandatory standards. Each product sold must be the same as all other similar products sold. Various quality control inspections and tests must be performed throughout the production process. And, proper documentation of design and quality control testing must be kept. It may turn out that the specifications are inadequate, but that will have to be dealt with post-sale.

Decisions about where to buy products or product components, U.S. or offshore, are also important. If offshore, quality procedures need to be implemented or modified for potential quality problems that have occurred with products from certain foreign countries.

Anticipating what kinds of documents will be necessary to prove to a plaintiff, a jury, or a government agency that the product complied with all specifications is critical. For consumer products, moreover, new conformity compliance documents may need to be created by someone in the chain of production. Lawyers can help create these compliance documents and advise the manufacturer on how long and in what form they should be retained.

## **Design Defects**

Design defects are the main theory of liability in most product liability cases. If a product's design is deemed defective by a jury, then all products with that design are potentially defective. Therefore, incorporating risk management techniques into the design process is critical.

One of the main ways companies design reasonably safe products is to engage in a full-blown risk assessment. This process can be expensive in terms of time spent by personnel and the cost of outside facilitators or risk assessment personnel. To help keep the cost down, company engineers can use various software and checklists to do what will probably be a sufficient risk assessment.

But a formal risk assessment may not be necessary for several reasons. First, a risk assessment done for one of the company's products could be used for other products within the same family of products or similarly designed products.

Second, reliance on industry standards and product designs of responsible competitors may be enough to create a reasonably safe design. Groups that create industry standards, in effect, are engaging in risk assessment in deciding on the final standards. And even though standards may be considered minimum requirements, compliance with relevant standards may be adequate in many instances.

Third, an analysis of accidents and lawsuits involving similar products made by your client or other companies can be useful in helping to quantify future risk and the likelihood of accidents and adverse verdicts with certain designs. Lawyers can certainly help obtain and analyze this information.

No matter what type of risk assessment is selected, risk management lawyers can help the manufacturer confirm that it considered all of the necessary factors, documented the process properly, and created the evidence of good faith and product safety consciousness necessary to minimize liability and defend against punitive damage claims.

## **Warnings, Instructions, and Marketing**

During the design process, all significant hazards need to be identified and designed out if possible. For those hazards that remain, a duty to warn might arise. Lawsuits alleging failure-to-warn are prevalent today. Manufacturers need to establish warning label guidelines that will allow for the creation of legally adequate warnings.

Lawyers can be helpful in identifying and analyzing how to comply with the many warning standards. In addition, lawyers can be helpful in analyzing what risks remain in the product and how to communicate risks effectively on a warning label. Also, as with the other areas, lawyers can be helpful in documenting the analysis underlying the warning labels attached to the product.

Remember that compliance with these standards is only a good start. It is possible to create deficient warning labels and still comply with the standards. Also the standards and the law do not answer a number of critical questions, such as those dealing with use of pictorials, foreign languages, location of labels on the product, need to test comprehension, and when warnings can be in the manual and not on the product.

Updating warnings and instructions can be time consuming. However, it can reap many benefits. For example, it can force the manufacturer to rethink how the product should be used and maintained, thereby resulting in design changes that make the product more user-friendly and safer. That is good for the manufacturer, seller, and user. And once done correctly, only minimal changes should be required in the future.

Last, risk management lawyers can review advertising, promotional literature, catalogs, websites, and other written marketing and sales material to be sure that unintended warranties and inappropriate marketing representations are not made which could create potential liability.

## **Contracts**

Contracts for sale and purchase should be reviewed by a lawyer to see if they provide the protection desired by that manufacturer or other entity in the supply chain. Provisions on consequential damages, implied warranties, remedies for breach of contract and breach of warranty, limitations of liability, and indemnification should especially be reviewed.

Lawyers also need to advise manufacturers on how to be sure their contractual terms and conditions govern the sale or purchase of the product. And lawyers should advise on whether the contract should deal with recall or retrofit and who is responsible to pay for and implement the program.

It is hard to get manufacturers interested in contractual review for product liability and risk management concerns. Manufacturers either have never had a contractual problem or have been unable to get suppliers or retailers to accept their terms and conditions.

The goal is to make sure that there are no surprises. By analyzing contracts, a lawyer can help product manufacturers or sellers understand the risks that they are assuming by their actions. So, if something bad happens, at least that was factored into the sales price or the way the manufacturer chooses to protect itself.

### **Post-Sale Duty to Warn**

In many jurisdictions in the United States and many foreign countries, product suppliers have a duty to warn product users of hazards discovered in their products after sale. Therefore, product suppliers must establish an appropriate feedback system to obtain product-performance information from customers, distributors, service personnel or sales personnel, wherever the product is sold.

In addition, product manufacturers can do many things before the sale to prepare for a recall if one is ever necessary. Doing these things will make the recall easier, cheaper, and more effective. And failure to be prepared might be used as an argument that the manufacturer had a disregard for safety.

Once a problem is discovered, it must be analyzed and an appropriate response or remedial action taken. Post-sale problems may require reports to governmental agencies. Because such reports may be used to defend claims and lawsuits, lawyers must be involved in analyzing this information and providing a legal opinion on an appropriate remedial action. The basis for the decision must be documented in the event that there is a need to describe it later.

These decisions are important because punitive damages can result from a post-sale program that a jury deems inadequate. Also, fines for failure to file timely reports with relevant government agencies have been significantly increased. Lawyers should be involved in the decision on what to report and how to properly document it.

Post-sale issues also include decisions made to improve manufacturing processes, designs, and warnings and instructions. Every time manufacturers make safety improvements, whether or not based on incidents, they must decide whether to make a change for just future products or to offer the improvement to prior customers. This is a critical decision that impacts future risk and should be made with the assistance of experienced counsel. Unfortunately, the law is mostly silent on the issue. So, in effect, the analysis results in the manufacturer's evaluating the risk of the product with the safety improvement against the risk of the product without it.

If safety improvements are made and not offered to prior customers, plaintiffs may argue that the improvement is evidence that the original product was defective. But informing prior customers of every product improvement can be very costly, unless the manufacturer charges for the new design (e.g., a safety guard) or new warnings and instructions. So a rational and defensible decision needs to be made.

### **Conclusion**

Manufacturers often underutilize risk management, and, in difficult financial times, such important protections can be more easily bypassed. But manufacturers must understand that product liability need not be inevitable. While it cannot prevent all problems, thoughtful risk management programs can reduce the chance of accidents and create a more defensible product and company in the event that some problem occurs

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