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Pharmaceuticals and Medical Devices: Products Liability Risk Management
Implementing Compliance Programs and Other Measures to Avoid FDA and State Law Violations and Minimize Tort Liability

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Today’s faculty features:
Kenneth Ross, Of Counsel, Bowman and Brooke, Minneapolis

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How to Prepare for Possible Product Recalls

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The 1977 CBEMA Paper on Electromagnetic Emanations
How to Prepare for Possible Product Recalls

BY KENNETH ROSS

In 2011, Australia and Canada adopted new product safety laws that require manufacturers and others in the supply chain to monitor their products in use, and to report safety issues and take appropriate corrective actions in certain situations. In addition, the U.S. Consumer Product Safety Commission has become more aggressive in levying civil penalties on companies who do not report safety problems in a timely fashion.

Therefore, it is more important than ever that companies be prepared to meet these obligations as they design, manufacture and sell their products. Being proactive and prepared before sale can save all companies in the supply chain significant amounts of money and effort, and make any recall or corrective action implemented after sale much more effective.

PRE-SALE PREPARATION

One of the most difficult things I’ve ever done is try and convince a manufacturer to prepare for a recall when they are first designing a product. This is not something that most manufacturers want to do. They are focused on trying to get a product into production and sold. Unfortunately, after the product has been sold, it is too late to do many of the practices discussed below.

Various entities in the supply chain should try to establish procedures before the product is sold so that each entity can, after sale, easily and efficiently obtain information, analyze it, make decisions about appropriate post-sale remedial programs, and implement any necessary programs.

Some of the most significant elements to build into the product’s design, manufacturing and distribution processes are traceability and marking procedures for use before and during manufacture and distribution.

To the extent possible, products and, especially, safety-critical components should be marked or coded so that anyone, including customers, can identify the product or component to be returned.

The Retail Industry Leaders Association and British Retail Consortium recently issued some safety guidelines for their suppliers. One of the requirements is that the supplier “shall have a system to identify and trace product lots including raw materials, components and packaging materials and follow this from the source of the incoming material through all stages of processing to supply of the product to the primary customer and vice versa in a timely manner.”
This is not easy to do and many manufacturers, especially those who have never had to recall their products, will wonder if the effort is worth it. Of course, in the event of a recall, this tracing will allow the manufacturer of the finished product or component part to narrow the affected population and clearly identify the population to customers. In that case, everyone benefits, from the manufacturer to the retailer to the consumer.

The next important consideration is for the manufacturer, in cooperation with all entities in the distribution chain, to design and maintain an effective database so that different types of entities, including product users if possible, can be identified. These databases must be updated periodically.

One of the most important and difficult tasks is for the manufacturer to set up a communications network before sale so that appropriate safety information is received. A manufacturer has a number of readily available sources of information anywhere their product is sold. Personnel should be trained to ensure that sufficient information is gathered concerning warranty claims, injury or damage claims, accidents, and near misses so that potential problems can be identified.

Personnel should also be trained to identify and clarify the information received so that it is accurate and substantiated. The manufacturer does not want to gather and maintain inaccurate and overstated complaints and claims that incorrectly make it appear that a problem exists.

Post-sale information, some of it unsubstantiated or even incorrect, can be posted by consumers on the Internet. This information needs to be monitored and followed up where necessary. Ignoring such information is risky, but following up on all alleged safety issues can be time-consuming and fruitless.

Manufacturers should think about what they will need to do to recall their product or withdraw it from the market. While the manufacturer will not know what the problem is before it occurs, it can at least think about the ways in which a recall or withdrawal would be communicated and be prepared to get the information out quickly.

For example, how will press releases, customer alerts, distributor bulletins, Web site postings, and questions and answers be used and how will the manufacturer be able to communicate this information quickly and efficiently to the appropriate people or entities. Another example of monitoring the communication stream is deciding whether the information in returned warranty cards is entered periodically or the company waits until a recall occurs.

As discussed below, the manufacturer must understand all legal reporting requirements for each country in which its product is being sold. The requirements have grown recently and are different from country to country. The result is that there may be a reporting responsibility in one country and not another. This may result in a recall in one country and not another.

Canada has a new reporting law that requires reports, in part, for an
occurrence in Canada or anywhere in the world that resulted or may reasonably have been expected to result in an individual’s death or serious injury. Australia’s new reporting law is likewise based mostly on an occurrence anywhere in the world for a product that is sold in Australia. One difference though is that “near misses” can trigger a report in Canada but not in Australia. In both Australia and Canada, there is an interesting question as to when a foreign manufacturer has a duty to provide occurrence information to Canadian or Australian entities to trigger a report.

In December 2009, the EU issued a new post-sale risk assessment process (see http://ec.europa.eu/consumers/safety/rapex/guidelines_states_en.htm) that should be used to determine if a report to the EU is appropriate and whether any corrective action is necessary. This process could also be useful in analyzing post-sale risks elsewhere in the world.

There is a new draft ISO standard dealing with recalls that will be published in 2013. It is called ISO 10393 and is being developed by ISO/PC 240. It is a “guidance standard” that contains an “international model code of good practice for consumer product recalls and other corrective actions.” This standard contains requirements for recall plans and policies that should be developed before sale.

Lastly, in 2004, the EU published a guide to corrective actions in Europe. This guide included suggestions for actions to take place before sale, many of them already discussed here. This guide is being updated and should be reissued in late 2011 or early 2012.

**POST-SALE PREPARATION**

As a manufacturer obtains and analyzes post-sale information, it must determine whether any post-sale action is necessary at any point in time. This includes reporting to the relevant governmental agency and possibly undertaking some form of recall.

Analyzing the information and deciding what it means is the most critical phase of this process. Many manufacturers use or should use risk assessment prior to selling their products. This process identifies the risk, probability of the risk occurring, consequences if it occurs, and methods to minimize the risk. Before sale, the manufacturer should make a best guess on the probability of the risk occurring. It is, of course, difficult to estimate the probability of an event occurring when it has never happened before.

After sale, the manufacturer is, in effect, considering new information from field experience. Post-sale incidents may indicate risks or consequences that were never imagined, or change the estimated probability calculated before sale. Redoing the pre-sale
risk assessment is a good way to formally recalculate the numbers and assumptions. Unfortunately, doing so doesn't really answer the question of whether and what type of corrective action is necessary.

For products regulated by a government agency, the manufacturer needs to identify the threshold for taking action. For example, the CPSC provides criteria for determining the existence of a defect and substantial product hazard. The criteria to be considered are the pattern of defect, the number of defective products distributed in commerce, and the severity of risk to consumers. Using these criteria will provide guidance to the manufacturer about what information to gather and how to analyze it. However, the CPSC provides little further guidance on this basic question, and expects the manufacturer to report a substantial product hazard or any suspicion that the product contains such a hazard.

After the manufacturer reports to a government agency, the agency will most likely, if not always, strongly encourage some type of corrective action. So, the manufacturer must be prepared, if it can as part of its report, to describe the actions that it believes will minimize the risk. It is possible, however, to propose that no corrective action is necessary.

Every entity needs to have experienced technical and legal personnel who routinely evaluate post-sale data and information and decide whether to report to the government and whether to undertake a corrective action or to undertake a corrective action even if no government agency is involved. If adequate pre-sale planning has occurred, implementing the program will be less difficult and more organized than if no planning occurred. Everyone will know what to do and when to do it.

Again, there is guidance on how to undertake recalls. I mentioned the EU guide to corrective actions. ISO 10377 will also provide general suggestions on how to undertake a recall. The CPSC also has a recall handbook. All of these guidelines discuss “best practices” and it is up to the individual manufacturer or product seller to determine which of these practices to utilize in a particular situation. Therefore, there is no such thing as an “off the shelf” recall plan that would make sense for sales of any product around the world.

Recalls can be extremely difficult and very ineffective, despite the best of efforts. There are no clear guidelines in the common law or even with government agencies about how effective a recall has to be. Recalls or retrofit programs with an effective rate of less than 10 percent have been deemed acceptable by the CPSC; the CPSC has said that the average response rate from consumers for most recalls is between 4 and 18 percent.

Virtually no recalls have 100 percent compliance. As a result, the manufacturer will have many products in the field that it has admitted or intimated are defective or at least pose a risk of injury. After an injury occurs and a lawsuit is filed, how will the manufacturer defend its product?

As the program is implemented, the manufacturer must think about how it will prove that its actions were reasonable and appropriate under the circumstances. Again, experienced personnel in this area can help and should be utilized.

CONCLUSION

Preparing for a recall before it occurs can significantly increase its effectiveness and lessen the costs and disruption to the manufacturer, distributor and customer. The effort will be well worth it if something happens. These efforts will also generate post-sale information that can provide insights into how your products and maybe your competitor’s products are being used. This will be helpful in making future product improvements. The end result will be safer products, less accidents, and more defensible products and actions if problems occur. 

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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 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 companies who want to and must 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 to the extent they believe that these requirements establish a “state of the art” that they want to meet.

This article will discuss the basic kinds of defects that can be alleged in any product liability case. Next, I will discuss the law as it pertains to compliance with standards. And finally, this article will discuss the EU directives applicable to electrical products and the effect of those directives on products sold in the EU and the United States.

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, 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.

Common examples of manufacturing defects are products that are physically flawed, damaged, incorrectly assembled or 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 will be liable. There are very few defenses.

Design Defects

A product is 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.

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 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.

**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 “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 the jury to decide. This makes it difficult for a manufacturer to know how far to go to warn and instruct about safety hazards that remain in the product.

**Post-sale Duty to Warn**

One other theory of liability that is very important in a product liability case is post-sale duty to warn. A manufacturer may have a duty, after sale, to warn customers about hazards the manufacturer learns about after sale. This duty can arise even if the product was not defective or hazardous when sold. This duty is clearly based on negligence and involves any of the three kinds of defects described above.

**LAW OF DESIGN DEFECTS**

There are two kinds of design defect cases: those involving “ inadvertent design errors” and another involving “conscious design choices.” Design errors are like manufacturing flaws and are treated easily 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 case 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.

**Test for Design Defect**

The predominant test in the United States for determining whether a product was “reasonably safe” involves, as mentioned above, 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 – 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. Also, as importantly, they provide a basis by which a manufacturer could evaluate the safety of its product before sale and decide what is “reasonably safe.”

**COMPLIANCE WITH STANDARDS**

Another complex area involves laws, standards and regulations. 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 different ones that must be reconciled, especially if the product is sold internationally.

Official laws and regulations, such as those passed by a state or national legislature, that apply to the product’s design must be complied with. If the product does not comply and this noncompliance caused the injury, then the manufacturer can be liable. Unfortunately, on the flip side, compliance with all applicable laws and regulations 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.

Similarly, industry standards and even certifications like UL are considered minimum. As a result, compliance with standards and certifications is not an absolute defense although it is pretty good evidence that the product was reasonably safe. Therefore, as with laws and regulations, the plaintiff can argue that you should have exceeded the standards. However, 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.
So where does this lead the manufacturer? You should meet or exceed all applicable laws, regulations and mandatory or voluntary consensus standards in the countries where you sell products. If you don’t or can’t, then document the reason and make a reasonable judgment as to why your product is still reasonably safe.

This is easier said than done. First, given the plethora of U.S. and international laws, regulations and standards, it is no easy task just to identify those that could apply to your product. Then, you need to figure out which ones take precedence over others where there is overlap.

In the European Union, there are ISO standards, EN/ISO standards and then Directives. Directives are similar to laws and EN/ISO standards have more authority than ISO and ANSI standards. So some are more important to comply with. But the bigger problem is figuring out which ones apply as there can be substantial overlap. Some U.S. and EU laws, regulations and standards are general and apply to a wide range of products. Some are much narrower. Generally, you want to first look to the narrower product specific document and then look to the more general requirements. The problem is figuring out where the “gaps” are in the narrower document that are then filled by the more general document. This is difficult to do and manufacturers need to also consider interpretations and guidances concerning directives and standards that are sometimes issued by government agencies, the EU and industry groups.

EU DIRECTIVES

In the United States, there are various industry standards, some of which are voluntary and some of which are mandatory in that some federal, state or local agency adopted the standard and made it the law.

In the European Union, they developed a variety of directives that pertain to health and safety. A manufacturer must meet the requirements of applicable directives and obtain a CE mark to sell their products in Europe. These directives must be enacted by each member country of the EU during a given period of time. However, each country can try to modify the directive to meet their own needs and desires. Some directives allow such leeway, others don’t.

One problem with these directives, some of which are described below, is that they may become worldwide safety requirements and raise the “state of the art” beyond what is required in the U.S. Therefore, if a manufacturer sells a “safer” product in Europe that complies with the EU Directives and a “less safe” product in the U.S. that complies with, let’s say, ANSI standards, this could be a problem. Obviously, the safer product constitutes a “reasonable alternative design” and can be used by the plaintiffs to support a case of defective design.

So, you need to be especially careful when you have a safer product sold in Europe or elsewhere. While U.S. law allows different levels of safety in a product (i.e. automobiles), you may need to justify the reasonable safety of your less safe product to a government agency or jury sometime in the future.

I want to describe some of the Directives that generally apply to electrical products.

General Product Safety Directive (“GPSD”)  

GPSD, Directive 2001/95/EC, was adopted in December 2001 for implementation no later than January 15, 2004. This directive establishes general safety requirements of many products, even those that would not be considered consumer products. This directive provides that manufacturers must sell safe products, defined as follows:

“safe product” shall mean any product which, under normal or reasonably foreseeable conditions of use including duration and, where applicable, putting into service, installation and maintenance requirements, does not present any risk or only the minimum risks compatible with the product’s use, considered to be acceptable and consistent with a high level of protection for the safety and health of persons,

There is also a reporting requirement for products that do not meet the above safety requirement. It says:

Where producers and distributors know or ought to know, on the basis of the information in their possession and as professionals, that a product that they have placed on the market poses risks to the consumer that are incompatible with the general safety requirement, they shall immediately inform the competent authorities of the Member States thereof...

There are also EU documents issued after 2004 which discuss the relationship of GPSD to products that fall under other directives, such as some of those discussed below.

The EU is undertaking further implementation and revisions to GPSD so that it conforms to their so-called “New Legislative Framework” which contains measures that have the objective of removing the remaining obstacles to free circulation of products between EU Member States.

Low Voltage Directive (“LVD”)  

The most recent edition of the EU’s Low Voltage Directive is dated December 12, 2006. It is designated “Directive 2006/95/EC” and includes a conformity assessment procedure that is applied to equipment before placing it on the market. Compliance with this directive should confirm that the equipment meets the EU’s Essential Health and Safety Requirements (EHSRs) which such equipment must
conformity assessment can be performed by the manufacturer or by a “notified conformity assessment body.” Improperly affixing the CE mark to a product has significant legal ramifications, including criminal sanctions.

As with U.S. standards, while meeting the EU’s requirements in these directives allows the manufacturer to attach the CE mark, these requirements are a minimum and an individual member state can impose additional safety requirements for products sold in their country. Unfortunately, this diminishes the usefulness of harmonized standards based on directives.

Also, the CE mark has no legal significance in the U.S. Compliance with EU Directives can be helpful in proving that the product sold in the U.S. was reasonably safe in the U.S., but there is no extra weight given to the fact that a European legislative body enacted these requirements. This is no different than the weight that is given to U.S. enacted laws and regulations.

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. EU requirements are, in many respects, much more rigorous than U.S. requirements. They are more detailed and overlapping and difficult and costly to comply with. Manufacturers could decide to sell only the safest product in the U.S. and elsewhere, even if that safer product is not required by laws and standards.

The trouble is that competitors might sell products with different levels of safety that might put the manufacturer at a competitive disadvantage. This is a costly decision for any manufacturer. Selling a safer product in the EU than you sell in the U.S. can result in significant liability. Selling a safer product in the U.S. that is not required by laws or standards may reduce liability by being more defensible. Unfortunately, it could also result in reduced sales that exceed any savings in litigation.

This can be a tough choice for a manufacturer from a financial, commercial and ethical standpoint. But one that must be made.

Kenneth Ross is a very experienced lawyer and consultant who advises U.S. and foreign manufacturers and product sellers on product safety, product liability prevention and legal and regulatory compliance. This includes advice on how to identify, evaluate and minimize the risk of liability, especially product and contractual liability. Prior to entering private practice, Ken was an in-house lawyer at Westinghouse Electric and Emerson Electric where he counseled on safety and prevention issues and managed litigation. Ken can be reached at kenrossesq@comcast.net. More of Ken’s articles can be accessed at www.productliabilityprevention.com.
Crisis Prevention, Preparation and Management

By Kenneth Ross

The goal of any business risk management process is to identify and quantify risk, identify programs that can help minimize that risk, and then implement programs that minimize the risk to a level that is acceptable to the business entity. The core of what many call “product liability prevention” or “product liability risk management” is to implement such programs that prevent or minimize product liability risk and to help provide “defensibility” if there is an incident and resultant claim or problem with a government agency.

Over the years, while product liability risks have been potentially great, they apparently haven’t been frequent enough or significant enough to get adequate attention from many companies. An additional reason may be that the risk is largely insured so the financial risk is perceived to be manageable. Despite that, you would think that the possibility, even if slight, of significant product liability litigation, a costly recall, some unpleasant entanglement with a government agency, and resulting bad publicity would be enough to encourage companies to be more proactive in trying to minimize such risks.

But the problem has been, as it is in other areas of risk, that the individual or business believes that the problem won’t happen to them. It will happen to the “other guy.” So, even if there are headlines about other companies suffering big problems, it may not be enough to get another company to act.

Recently, the problems, as evidenced by daily headlines, have become so significant that companies really need to take these potential problems more seriously. Product liability prevention has always been important, but now, for some companies, in some industries, the process should be elevated to crisis management. But “management” is too narrow in that it implies that a crisis can’t be prevented. The concept should more aptly be described as Crisis Prevention, Preparation and Management (“CPPM”).

While the goal is to prevent the crisis in the first place, having a CPPM program in place will, when implemented, minimize the chance of business and legal problems occurring and help ease their effect if they happen. Now, of course, while these problems can occur in many areas – industrial accidents, criminal activity, loss of proprietary data, environmental accidents – the focus of this article will be on product liability related problems.

A CPPM program is similar to a product liability prevention program – it is just broader and involves more professions. It assumes that a crisis can result in much bigger problems than just product liability lawsuits and possibly a recall. For example, additional legal and business problems can arise with any significant product liability issue such as worldwide media coverage, multi-national government investigations, whistleblowers, shareholder lawsuits, consumer class actions, public disputes with suppliers, vendors, and customers, and backlash from customers and the public, including consumer boycotts.

These problems make the typical product liability issues pale in comparison. And this is especially true as the costs of dealing with most of these other problems are not insurable. The future viability of the company involved and even an industry can be put into jeopardy by one incident. The nuclear industry never fully recovered from Chernobyl and Three Mile Island.
The oil drilling industry probably will not be the same as a result of the oil spill in the Gulf of Mexico. Exxon Valdez and Bhopal have special meaning with the public and their negative connotations can never be erased. And everyone knows what happened to the Challenger Space Shuttle and even the Titanic.

The above are single incidents of great magnitude and are not product liability cases. However, even in product liability, the following products and events elicit many feelings among the consuming public and resulted in huge liability and costs for their manufacturers: Audi 5000, Ford Pinto, Firestone 500 tires, Ford Explorer/Firestone tires, Vioxx, tobacco, asbestos, Mattel lead paint recall and the peanut recall. Many of these products and companies are by business school ethics professors to teach about what a company should NOT do.

It seems that after each of these events or series of cases occurred, information comes out in the litigation, in the media and maybe in Congressional testimony about the company or governmental agency either not properly evaluating risk, not being prepared to take appropriate measures to deal with the risk if it happens, or not acting diligently once it occurs. And you wonder, what went wrong? None of these companies wanted these problems to occur. In the situations mentioned above, they certainly knew the consequences of product failures. So, did they improperly evaluate the probability of the risk occurring? Did they deem the risk low enough that it was an acceptable risk? Or did they underestimate the severity if it occurred? In some cases, companies cut corners to save money or time and hoped for the best. In other companies, the pressure to achieve short term profits colors all other actions. And those responsible get promoted, not fired, in effect outrunning their mistakes.

Risk assessment is the most difficult part of crisis prevention. How do I predict the possibility of something happening that hasn’t happened yet or only happens infrequently? Will it happen to my company or my competitor or not at all? How bad will it be if it happens? How much time do I spend preparing myself for an event that may not happen?

Especially in these financial times, it is difficult to get companies to spend money preventing problems they’ve never had. However, if they seriously calculated the potential cost of a significant problem, both financial and reputational, they might be inclined to do more.

What more can they do and should they do? Do they need a full-blown CPPM program or something less? An initial analysis of the company and the risks they have experienced and could be subjected to can help answer those questions.

Crisis Audit

The first task in determining whether a program should be established and what form it should take is to undertake a product liability crisis audit. This will help identify and quantify risks and distinguish normal product liability problems from much bigger problems that truly can rise to the level of a crisis. This analysis requires the business people to define what they believe to be a crisis for their company and shareholders and their industry in general. Different companies may come to a different conclusion about the same problem.
Given the sensitive nature of the audit, I suggest that an outside lawyer be involved directly in asking the questions. This will help to keep the answers privileged as they will eventually be used by the lawyer to make legal recommendations on what kind of program should be established. Use of in-house lawyers is probably not a good idea as the privilege may be subject to challenge and some of the questions might be sensitive and could impact future relations with fellow employees.

This lawyer will need to have sufficient general familiarity with the company and expertise in product liability wherever the product is sold. The lawyer will need to understand prior legal events involving the company and have an understanding of future potential legal risk. And the lawyer will need to be very familiar with the whole range of preventive techniques available to companies.

The lawyer may want to consult with a crisis management expert (there are CM experts, but it also may include public relations, insurance, regulatory, and recall management experts) before doing the audit to make sure all of the correct questions are asked. And the lawyer should try to identify other problems similar companies are experiencing. Anticipating future potential areas of legal risk is highly speculative, but very helpful. An example of one such area right now is nanotechnology (See http://www.nanotortlaw.com/nanoblog/blog.aspx).

When responding to these questions, in a sense, the business controls its destiny. It gets to decide how much risk it is willing to assume and how much of the risk they want to try and minimize. This will include an analysis of their ability or inability to identify the problem early before it turns into a crisis. And also whether the company has the ability to quickly contain the problem before or shortly after it turns into a crisis.

After obtaining the answers, outside counsel can turn again to the crisis management experts before making recommendations on what kind of program could be established. These recommendations can be presented orally to the in-house lawyers and key corporate personnel to get their reaction. The recommendations can then be modified to reflect the company’s willingness to accept risk and spend money on these activities and then included in a final report to the General Counsel.

This process will help the company decide how prepared they need to be and what preparations need to be taken. The following are some questions related to product liability that need to be answered by counsel and the company:

- Do they need a designated crisis management team? Who should be on it? Should there also be other groups, for example a product safety committee, which deal with similar problems of a lower magnitude?
- What kind of training does this team and others in the company need to have to help them identify a potential crisis and how to minimize it?
- What are the triggers to start the program? Does the team meet regularly to review potential problems or wait until a crisis hits? Do the other committees decide when to escalate a problem to the crisis committee?
• Does the company need to have a public relations company experienced in crisis management ready to jump in at a moment’s notice to deal with the media and shareholders and customers? Should this person participate in the crisis committee’s regular meetings to help determine the anticipated media reaction to certain potential events or actions?

• Does the company need experienced government relations experts on board to immediately deal with any local, state or federal issues that may arise? And should they be involved in regular deliberations of the crisis committee?

• Should the company have a recall management company on call in the event a recall needs to be quickly implemented?

• What involvement should lawyers have in the implementation of any program? Should they be involved in the regular meetings of the crisis committee or other related committees?

• What role do these committees have in approving company actions or inaction BEFORE the crisis if such actions or inaction can turn into crises in certain situations?

Analyzing and developing the need for such a program should be done under the supervision of outside counsel, but once the program is implemented, none of it is privileged. Documents describing the program are created in the normal course of business. Despite that, counsel needs to be involved in their drafting as evidence of the program will be used against the company after a crisis arises.

The program shouldn’t look like a crisis is inevitable, but is being instituted out of an abundance of caution. The program should also be generally described to those in the distribution chain so they understand their duties and responsibilities in implementing the program. There are risks in how it looks to have a stable of lawyers, PR experts, and recall management experts at the ready before you have problems. However, it should be portrayed as just another form of insurance that will be helpful in the event of a problem.

Pre-sale Preparedness

In product liability, many crises involve recalls. Therefore, recall preparedness is a critical component of any CPPM program and needs to be done before the product is sold. This helps the manufacturer to more easily and efficiently obtain information, analyze it, make decisions about appropriate post-sale remedial programs, and implement programs. Many of these procedures cannot be implemented after sale of the product.

Below are some of the things a manufacturer should consider doing before sale. Not all of them may be required for a typical recall. However, for a recall that could result in a crisis, these techniques could go a long way to prevent the situation from turning into a crisis.

a. Products should be designed and tested with post-sale programs in mind. For example, the product should be designed in modules so that components that prove to be defective can be replaced without having to replace the entire product.

b. Products should be manufactured using traceability and marking procedures that are utilized pre-manufacture, during manufacture, and during distribution. Products or components should be marked or coded so that anyone, including
customers, can identify the product to be returned. RFID technology should be considered if appropriate.

c. The manufacturer should develop a post-sale exposure audit where the manufacturer summarizes worst-case scenarios and develops initial strategic action plans for each scenario. This would include a determination of safety critical parts and raw material and what can happen if they fail.

d. The manufacturer must develop an information-gathering network before sale so that appropriate information is identified and analyzed. This procedure is so important that it is discussed in more detail below.

e. The manufacturer’s lawyers should help to analyze and create contracts and agreements with upstream and downstream entities which anticipate and deal with post-sale issues such as information that must be supplied, who has the responsibility or authority to report to a government agency, what approvals are necessary to undertake a remedial program, who pays for the remedial program, etc. Also to be considered are insurance and indemnity provisions.

f. The manufacturer, in cooperation with all entities in the distribution chain, should design and maintain an effective product and customer database so that different levels of customers in the chain of distribution can be identified quickly. These databases must be updated periodically.

g. Press releases, customer alerts, distributor bulletins, website postings, and questions and answers to be used by management could be drafted before sale or, at least, not too long after sale. Methods to communicate this information quickly and efficiently to the correct people or entities should be developed at this time. For example, a manufacturer should be able to almost instantly communicate (by broadcast fax or email) a message to distributors and retailers requesting that they embargo sales of a particular product. This will prevent sales of unsafe products and minimize the number of products that have to be recalled. See http://money.cnn.com/2010/07/07/news/recall_insurance_crisis_pr.fortune/index.htm.

h. The manufacturer needs to develop criteria on the types of remedial programs that may need to be implemented and then develop procedures and processes to implement each of these programs. Recall is not always necessary. And, there are different levels of recall, depending on the level of risk and difficulty finding the products.

i. The manufacturer should consider record creation and retention procedures so that appropriate documents are created that prove the manufacturer’s due diligence in identifying the problem and taking care of it. This will include determining the record-keeping requirements of all relevant government agencies or applicable standards or directives.

j. The manufacturer could consider creating procedures to reintroduce the product to the market. This involves an analysis of the worst case scenarios and how to test
and modify the product quickly and design communications to restore and strengthen the product’s reputation among the distributors, retailers, and customers.

k. The manufacturer should even consider internal recall training, drills, and full-scale mock exercises. When a crisis occurs, it will prove to be time and money well spent. See www.expertrecall.com for more information.

A manufacturer needs to be careful that this pre-sale planning does not appear to be an admission that the company expects critical safety problems with this product and is just planning for the inevitable recall. The planning needs to be routine and consistent with a product safety policy. It can also be justified to comply with U.S. and foreign laws and regulations or retailer safety standards that require a manufacturer to be better prepared to recall its product. And maybe it is also being done to convince the insurance company to lower premiums or the self-insured retention.

Post-sale Preparedness

One foundation of a CPPM program is establishment of an information network that will allow a company to determine how its product is performing in the U.S. and world marketplace. This information is necessary for the manufacturer to ultimately make decisions about what, if any, post-sale action might be necessary.

This network must encompass product safety information received anywhere in the world. The regulatory and common law requirements apply to information that the company obtained or should reasonably have obtained anywhere in the world that identifies an unsafe condition. Therefore, anything less than a “reasonable” effort at obtaining information may be considered inadequate by the jury or government agency or media.

Some laws and regulations and industry standards set forth post-sale monitoring requirements. These need to be considered in setting up such a program. These include the kinds of information that should be considered and the kinds of documentation that need to be kept. As I’ve previously written, many foreign governments have enacted or will be enacting legislation requiring manufacturers to report to their government even if the accident occurred outside of their country. Australia’s new product safety law, effective January 1, 2011, does exactly that.

Outside counsel can play an especially useful role in assisting the company in setting up such a program. The program needs to comply with any applicable regulatory laws anywhere the product is sold. And, to the extent it is possible to anticipate, counsel should advise on what kind of program is likely to be defensible? The analysis that goes into establishing such a program and how it was implemented should be documented so that later, if necessary, someone can testify as to why the company did what it did or couldn’t do what it didn’t do. This is necessary since, with 20/20 hindsight, anyone can argue that the company should have done more.

Taking action

Once a manufacturer has obtained all relevant information, it must determine whether post-sale action is necessary. This includes reporting to a relevant government agency and undertaking some form of remedial plan.
Ideally, a corporate or divisional product safety committee or crisis team should analyze the information. This committee should be made up of representatives from various areas of the company, including engineering, service, sales, marketing, and legal. It is also very important that the lawyer who is advising the committee be experienced in product liability and regulatory law of the countries where the affected product was sold. Last, additional outside resources such as public relations and government relations experts may need to participate in some aspect of the committee’s deliberations.

If dealing with a crisis could result in litigation, a company lawyer could chair the crisis committee and keep the minutes so as to try and keep the deliberations privileged as work-product. Involving outside counsel who might help defend the company in such litigation at this point could be helpful in making decisions and developing documentation necessary to present a defense.

Analyzing the information and deciding what to do is the most critical phase of this process. Many manufacturers use or should use risk assessment prior to selling their product. After sale, the manufacturer, in effect, is plugging new numbers into this risk assessment. Post-sale incidents may indicate risks or consequences that were never imagined, or increase the estimated probability calculated before sale. Redoing the pre-sale risk assessment is a good way to formally recalculate the numbers and assumptions. Unfortunately, that doesn’t really answer the question of what action is necessary.

Determining whether post-sale action is necessary under the U.S. common law requires applying the factors identified in the case law to the facts learned through the information-gathering network and the results of the redone risk assessment. It is a negligence-based balancing test. For products regulated by a government agency, the manufacturer needs to first identify the threshold for reporting and taking action and then work with the agency on whether a remedial plan is necessary and what that plan would entail.

Post-crisis audit

After a crisis or legal problem that could have turned into a crisis is over or mostly over, a post-crisis audit is appropriate. This audit will consider evaluating things such as what can be done to prevent a future similar crisis or identify it earlier, what worked and didn’t work in handling this particular crisis, what can be improved, what additional personnel need to be involved, what personnel don’t need to be involved, and what documentation needs to be improved.

As with the pre-crisis audit, this audit can be undertaken under the direction of outside counsel so the lawyer can recommend improvements in the program and keep the audit results and those recommendations privileged.

Conclusion

With a 24-hour news cycle and resultant hungry investigative reporters and publications, aggressive plaintiff’s lawyers looking for the next big series of product liability cases or shareholder derivative actions, and more retailer and customer awareness, the threat that a routine problem can turn into a crisis has increased. Most of the crises we read about in the press could probably have been prevented or, at least, handled better once they occurred.
The consequences of not doing an adequate job can be enormous. Some upfront investment of time in CPPM can result in the company taking less risk and being prepared if the risk occurs. This will benefit the company and its personnel and the company’s suppliers, vendors, customers, and shareholders. It might even save problems for governments and society in general. It could actually turn out to be a good return on what can be a relatively modest investment.

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i Some recalls are actually helpful for a company. Johnson and Johnson’s 1982 Tylenol recall and McDonald’s recent recall of Shrek glasses have been cited as examples of superior corporate responsibility. Unfortunately for Johnson and Johnson, they have been severely criticized this year for their Tylenol safety problems that resulted in a recall. See http://money.cnn.com/2010/06/07/news/companies/mcdonalds_recall_strategy.fortune/index.htm.

ii I will focus on product liability, but many other substantive legal areas could be included in any crisis audit.
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
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.