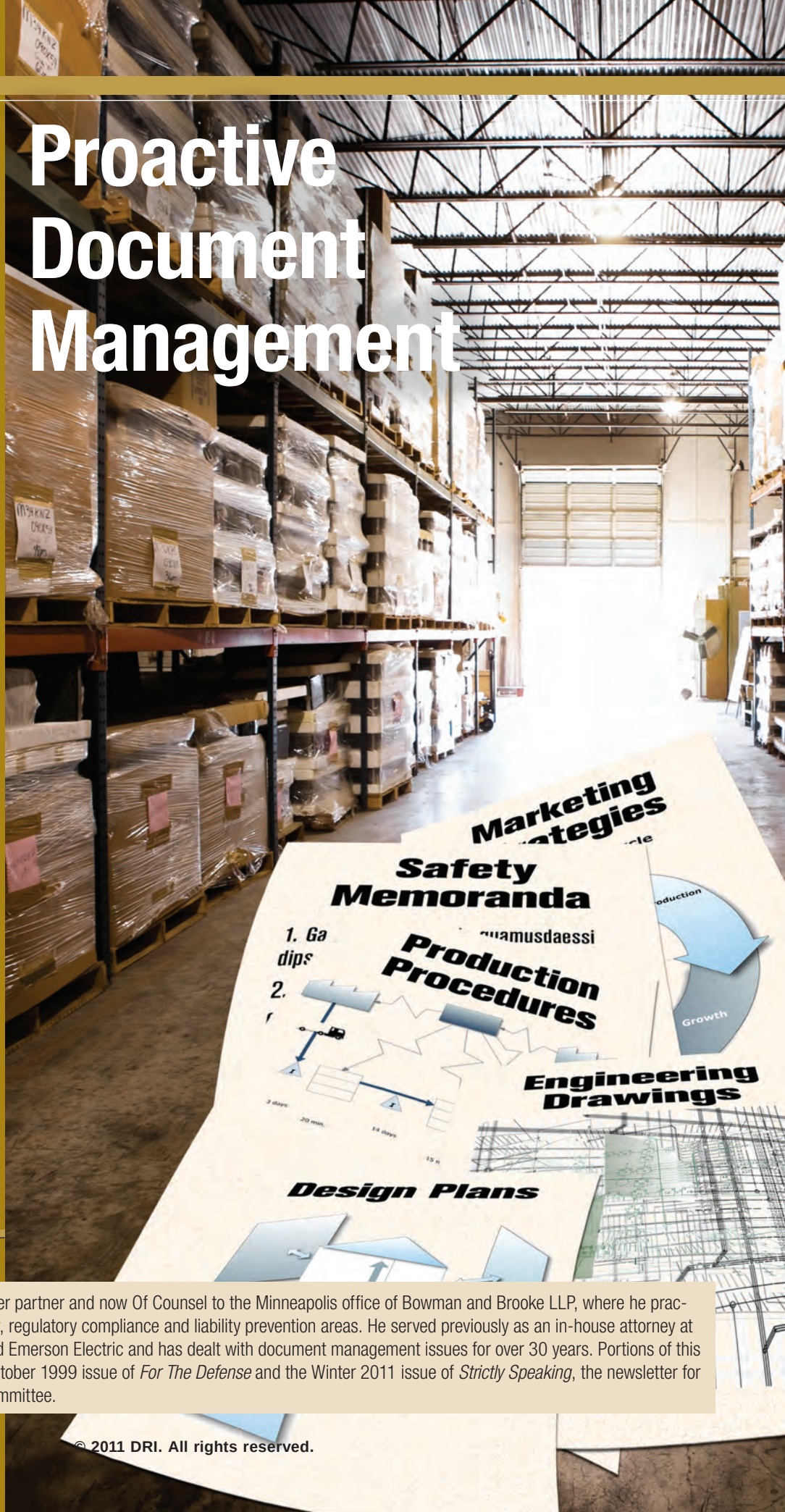
A Program for the Twenty-First Century

# Proactive Document Management

By Kenneth Ross

**A** manufacturer must proactively establish a system that ensures compliance with legal requirements and results in the creation of a story of the development and life of a product.

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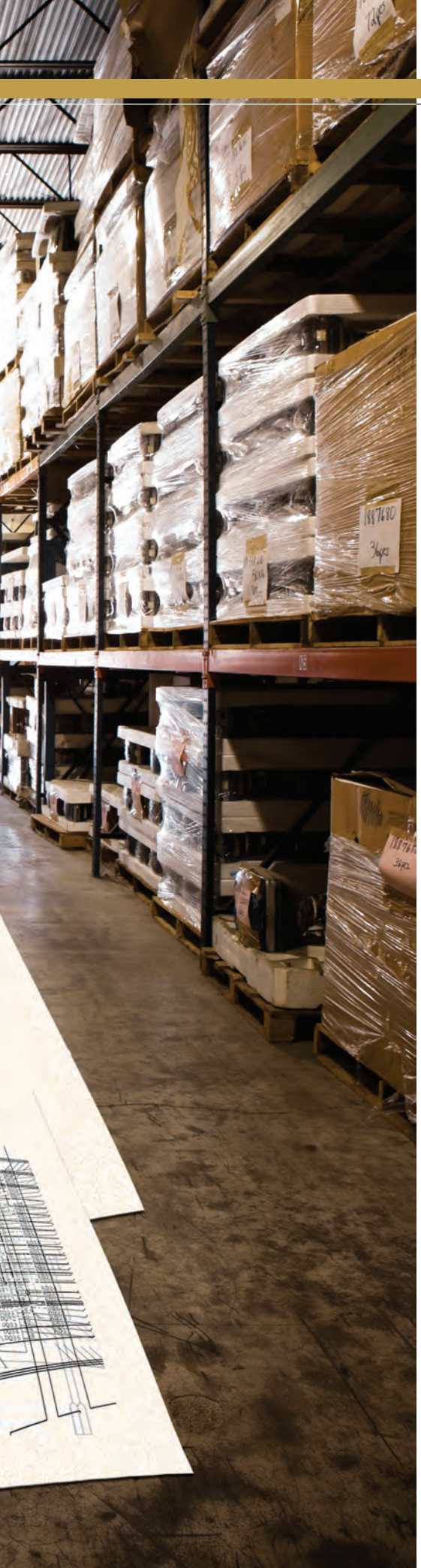

Documents, including hard copies or electronic records, are the lifeblood of any corporation. While employees come and go and change jobs within an organization, the design plans, engineering drawings, production procedures, safety memoranda, and marketing strategies that they have created represent a historical record of the activities of that particular entity. Documents can merely record this history, or they can significantly help or hurt a manufacturer or product seller, especially in the event of product liability litigation.

Plaintiffs' attorneys try, through the discovery process, to identify and obtain harmful documents that they can use to achieve large settlements or verdicts against manufacturers. Some manufacturers are harmed because they failed to create documents showing their concern for safety. Perhaps even more frustrating, documents reflecting safety activities were created but then destroyed before litigation arose. Such documents can sometimes be very helpful in defending product liability cases.

This article will discuss the importance of documents in designing and manufacturing products and how the existence of or lack of drawings, plans, and other records has hurt manufacturers, as well as how documents have helped manufacturers in their defense. Then, the article will discuss document management systems, legal requirements to create and retain documents, and ways in which employees can affirmatively create helpful documents—and not create unnecessarily harmful documents.

This article updates an article that I wrote for *For The Defense* in 1999. Many things have changed since that time, especially the pervasiveness of electronic records that have changed how manufacturers create, store, and destroy these records and other documents. In addition, the growth in popularity of the Internet and social networking media has created more opportunities for the dissemination of potentially harmful information to the government, to plaintiffs' attorneys, and to potential plaintiffs. Retailers and standards groups have started demanding that manufacturers employ state-of-the-art safety processes and provide documents evidencing compliance. And last, product liability and product safety laws have proliferated around the world, making it necessary for a manufacturer to keep track of and document everything that is going on with its products inside and outside the United States.

Despite these changes, the main message is the same—a manufacturer must create documents to confirm its efforts to make safe products. In doing so, a manufacturer should think about how it might need to tell its story to a jury, customers, plaintiffs' attorneys, or the government and to create documents that will accurately and completely depict these efforts.

## Importance of Documents

During the design, manufacturing, and marketing phases, a manufacturer's goal is to make a product that reasonably balances the risk of injury from use of the product against the product's functionality, utility, durability, price, and other attributes. If accidents do occur and product liability claims and litigation result, hopefully a manufacturer will have evidence that it did sufficiently undertake measures to make a product considered reasonably safe. Thus, a manufacturer should have created and retained documents that evidence its interest in safety and regulatory compliance and describe procedures for evaluating a product's reasonable safety.

Since the conduct of a manufacturer may be admissible and used by either a plaintiff or a defendant to prove its case, a manufacturer needs documents that describe and memorialize the steps taken by the manufacturer to present an effective defense and to prove that the manufacturer was careful and prudent. Many lawyers, however, feel that documents that analyze risk and describe design, production, and marketing processes only hurt manufacturers and can rarely help their case. So they may not encourage manufacturers to create or retain documents, especially those

that deal with safety. Invariably, those lawyers view such documents as harmful and difficult to explain. Those lawyers do have a point, especially when engineers challenge and question safety during a product's development phase. This dilemma has been described as follows:

> The existence of a questioning memo from a designer concerned with safety aspects of a new product, combined with evidence that the designer's point of view was adequately considered, is probably better in most situations than a "blank record" suggesting that safety-related areas were never considered at all, or that the records have been sanitized to prevent embarrassment in court.

Kolb & Ross, *Products Safety and Liability: A Desk Reference*, at 91 (1980).

**Manufacturers… need to train employees on how to write defensively and how to follow up on documents when someone raises safety concerns.**

Each manufacturer must decide how to balance the risk of retaining documents that hopefully will help but could, in the wrong hands, be misconstrued, taken out of context, and used against the manufacturer in a product liability lawsuit. The goal is to create helpful documents that are not unnecessarily harmful.

### Documents That Hurt

Instances where manufacturers have suffered substantial losses because of "bad documents" are well-known to all lawyers. Not only can such documents result in significant liability, they can also lead to widespread negative publicity and notoriety, and opponents may use them in claims and lawsuits subsequently filed against manufacturers.

A leading scholar of product liability law, David Owen, recognized this conundrum:

> Manufacturers necessarily create massive documentation of their design and production processes, sometimes amounting to millions of pages of notes, memoranda, and correspondence over the life of a product. Especially during the initial design of the product, but also as information returns on the product's performance in the field, reports of many instances of one problem or another will be documented, acted upon, and filed away. In fact, the more a manufacturer is truly concerned about its product's safety, the more it will encourage self-criticism and "negative" analyses of the product within the company.

David G. Owen, *Problems in Assessing Punitive Damages Against Manufacturers of Defective Products*, 49 U. Chi. L. Rev. 1, 17 (1982).

Owen went on to write that

> Cost-benefit analysis is fundamental to the design engineer's trade…. Many hundreds of such choices are made by design engineers in the production of a single complex product, and each such decision involves a range of trade-offs between cost, weight, appearance, performance capabilities…, and safety in one type of accident versus another…. Although much of this decision making involves the application of proven scientific principles, much is art, and some by its nature can be little more than trial and error.

*Id.* at 24–25.

Despite the wisdom of Owen's observations, juries still sometimes react angrily toward corporations that consider the value of lives. One troubling aspect of a jury's reaction to such analysis is that product liability law and safety engineering principles *do* allow manufacturers to consider cost when determining how safe to make a product. *See Restatement (Third) of Torts: Products Liability*, §2 cmt. f. However, what juries apparently don't like is that the documents do more than consider cost and safety and instead associate product cost with the value of human life and the value of settling cases for presumed future incidents.

The lesson defense attorneys can draw from such cases is *not* that manufacturers should avoid creating or retaining documents concerning design and manufacturing processes and procedures. Rather, the lesson that manufacturers should draw is that they need to train employees on how to write defensively and how to follow up on documents when someone raises safety concerns. Manufacturers should do this not only for litigation purposes, but to record clearly and accurately the reasons for design and manufacturing decisions. This is the proactive part of document management.

### Insufficient Documentation Can Hurt

In addition to having documents that cause problems, scant documents can also hurt the defense of a case. For example, if a manufacturer performs an adequate safety analysis in its design process, it should also create proper records so that it can defend its process later in court. A manufacturer needs to do appropriate testing and create documents that describe the tests and results. Doing the tests in "your head" is not enough, especially when a design is challenged many years later.

Even if an engineer can remember doing safety testing, a jury may not believe that a manufacturer performed the tests if the manufacturer did not create or keep documents about the tests. And if safety was so important, why didn't a manufacturer keep documents evidencing the testing? In addition, in many cases, no one is left who remembers the reasoning. Assurances that whatever tests an engineer did must have been correct may not sway a jury.

In addition, one of the most significant defenses to a product liability claim is that there were no prior, similar accidents involving the product. However, without good documentation supporting the defense that similar accidents did not happen, an opponent can defeat efforts to present this defense.

A majority of jurisdictions require a substantial showing on the part of a manufacturer to have evidence of no prior accidents admitted. Courts generally use two criteria to determine if they will allow that evidence. First, a defendant must offer proof that the lack of accidents pertained to products that are substantially identical to the one at issue and used in sufficiently similar settings and circumstances to those surrounding the product at the time of the accident. Second, the defendant must demonstrate that a communications system was in place whereby accidents could

or would be reported or recorded. A manufacturer will need documents to prove both of those criteria.

### Documents That Help

As mentioned above, I have heard litigators say many times that corporate documents always hurt their defense and rarely do they help. Of course, the only documents that a plaintiff will want to have admitted will help its case. And, if a company has documents that will help the company's case, a plaintiff will do what it can to keep those out or maybe not raise issues that will allow the manufacturer to have these "due care" documents admitted. Despite that, in some cases documents can help.

It was mentioned earlier that a systematic record of prior accidents can support testimony that there have been no prior, similar accidents. But I also firmly believe that documents evidencing a concern for safety and "trying to do the right thing" will go a long way toward at least defusing any thoughts by plaintiffs of seeking punitive damages. Documents proving compliance with voluntary safety standards are very important. And after sale, documents evidencing efforts undertaken in a recall can be crucial in defending the adequacy of the program, especially when you can prove that the plaintiff received a recall notice before the accident.

The reality is that if your client doesn't have any safety programs or if your client has safety programs but threw away the documents, the plaintiff may become overly excited about its case. And, if your client has safety programs and has the documents to prove it, the plaintiff will likely obtain the documents and you will have to defend them. I'd rather defend a comprehensive and documented safety program any day.

### Documents on Postsale Issues

The potential liability of a manufacturer or product seller for common law negligence after sale of a product is well-known. In addition, current U.S. regulatory and common law requirements apply to information that was obtained or should reasonably have been obtained that identify an unsafe condition. The potential liability for violations of regulatory laws is growing as more foreign governments implement consumer product safety legislation. All of these laws contain a duty to report to the government if threshold safety events occur. This enhanced focus makes it even more important that a manufacturer gather, analyze, and document safety information received from anywhere in the world.

Anything less than a "reasonable" effort to obtain and analyze postsale information may be considered negligent by a U.S. jury in determining whether a manufacturer should have known about the problem before an accident occurred or by a government agency in deciding whether the manufacturer should have reported the safety issue to the government. Therefore, deciding what is reasonable under the circumstances is important to determine and document.

Manufacturers will receive documents and information from consumers, government agencies, consumer groups, and plaintiff's attorneys. The growth of the Internet and social networking media have made it even easier to find this information if you are looking for it and easier for manufacturers to receive this information from those who want to communicate with them about it. Many of these documents and reports will be unverified, overstated, inaccurate, and incomplete. Manufacturers will have to decide how to follow up and investigate these reports to get to the truth and minimize the unnecessary and unsupported problems that they could cause.

It is very important for a manufacturer and others in the chain of production and distribution to establish procedures to identify, review, and analyze all of the information that might relate to the safety of a product in use and to funnel it to trained personnel to evaluate so that the manufacturer can make a decision about appropriate actions. In addition, this will help a company respond to inquiries concerning safety made by the government, the press, or consumers. Being aware of all information—good and bad, true and untrue, complete and incomplete—can be helpful as long as a company can sort out the important information and adequately evaluate and document it and take any warranted corrective actions.

## Document Management Programs

Here are some guidelines that you may want to discuss with your manufacturer clients to establish effective document management systems. Document management includes the development of guidelines and procedures for determining which documents to create, which documents not to create, which words to use and not to use, how long to keep documents, when to destroy and how to destroy them, and in which form a company should retain documents.

The pervasiveness of electronic records as the only record type that many manufacturers now create and keep makes developing a document management system difficult. And, the document management programs of many manufacturers simply address when to discard or delete documents. Such a narrow focus is inadequate; a document management program should consider many other elements, and without proper handling, those elements can lead to liability. Any manufacturer concerned about the use of documents in future litigation should implement a comprehensive document management program as part of an overall product liability prevention program.

It is helpful for each manufacturing entity within a corporation to establish a document management policy and guidelines. This policy should confirm that employees are encouraged to bring to management's attention, orally or in writing or both, all good and bad information about the design and manufacturing process of which they are aware. In other words, a company should encourage employees to reveal potentially damaging information, bringing it to the attention of supervisors rather than hiding it.

The policy should also contain guidance on the kinds of documents that employees should create and how to compose those documents so that they meet the criteria of "defensive writing," discussed more below. It should contain retention schedules for all documents, including electronic records. The policy should use clear, unambiguous language so that all affected employees will be able to comply.

In addition to writing and distributing the policy internally, a company should periodically perform a compliance audit to show that management is serious about compliance and so that the company can identify and correct problem areas. In some companies, employees may slight activities

that don't help get products out the door if management does not establish a specific audit requirement to confirm compliance.

Another essential part of managing a document program is educating employees about the policy and how to comply. A company's training must clearly show that the company is interested in learning about all good and bad information concerning its products, and its documents should reflect the concern that it has for selling safe products that comply with all applicable laws, regulations, and standards.

**Documents evidencing** efforts undertaken in a recall can be crucial in defending the adequacy of the program.

### Document Creation and Retention Requirements

Federal and state governments have probably issued thousands of legal requirements for the creation and retention of documents. The federal requirements have been gathered and published by CCH, Inc., in *Guide to Record Retention Requirements in the Code of Federal Regulations as of January 2006*. The state and federal requirements are also gathered by the Information Requirements Clearinghouse (IRCH), (http://www.irch.com/). Every manufacturer doing business in the United States must be acquainted with the safety and quality-related document creation and retention requirements imposed by federal and state statutes and regulations.

In addition, a manufacturer must consider mandatory and voluntary standards or certifications in the United States and elsewhere. For example, a manufacturer must develop and maintain certain documents to confirm compliance with the European Union (EU) Machinery Directive to attach a CE mark to a machine sold in the EU. And any toy manufacturer selling into the EU must comply with the new Toy Safety Directive, which requires that a risk assessment be performed and that documentation of this assessment be kept for 10 years.

Documentary evidence of compliance with such standards may strengthen a defendant's case in a product liability lawsuit. You can use that evidence to confirm that a manufacturer took steps to ensure that its products were reasonably safe and complied with all applicable laws, regulations, and standards. In other words, both the legally required and voluntary documents reflect that a manufacturer considered safety during the design and creation of a product.

### Creating Documents for Defense

Documents relevant to product safety and liability generally fall into seven categories:

1. Product design and development, which includes labels and instructions;
2. manufacturing and quality control;
3. merchandising and sales;
4. service and installation;
5. postsale, which includes complaints and incidents;
6. personnel; and
7. management and coordination.

Documents detailing a manufacturer's activities in the above categories will present a comprehensive history of the life cycle of a product from its design to manufacturing, to its selling and postsale life.

Each of these documents should be prepared in such a way that they do not unnecessarily increase potential liability in the event of claims or lawsuits. This is usually called "defensive writing."

Writing defensively does not mean that a manufacturer tries to hide bad information or evidence or shades the truth. On the contrary, a company's policy and educational programs must stress to employees that they should raise all issues, good or bad, during the development of the product.

The documents must portray correctly and accurately a manufacturer's rationale for designing and making its product. A record of this rationale is necessary for designing future similar products and for good historical corporate record keeping. In addition, if the content of some documents challenge or discuss safety, they must be written so that they do not create misleading impressions and someone cannot quote from them out of context so that a plaintiff could use the quotes unfairly against a manufacturer in litigation.

Those employees who draft the manuals, plans, specifications, and other documents—the "writers"—should avoid legal terms that describe theories that a plaintiff's attorney may present to a jury in a product liability lawsuit. These terms include "defect, negligence, misrepresentation, and reckless." Use of these and related legal terms by internal writers may lead a jury to decide that a company has admitted that its product is defective or unreasonably dangerous or in some other way legally deficient.

While a writer will have a chance to tell a jury why the word "defect" did not really mean defect in a product safety sense, including such a loaded word in, for instance, a report on the development of a new product, gives a plaintiff an advantage in presenting his or her case to the jury.

Additional phrases and words to keep out of documents include overstated expressions, characterizations, or opinions. They can cause problems for a company. For example, writers should not use phrases such as "occurs often" or "occurs frequently" when an engineer has only noticed two or three occurrences. Don't use the word "catastrophic" in connection with a product failure unless it truly was catastrophic. "Catastrophic" may be a commonly understood term among engineers, but it may be too strong when heard by a jury.

Another term to avoid is "crisis." Writers trying to get the attention of their supervisors may want to call every problem a crisis. This is unnecessary overstatement; it suggests that a company is having huge problems all the time. Similar terms are "smoking gun," "ticking time bomb," and "sitting on a powder keg." They are inflammatory and unnecessary.

In addition to choosing words and phrases carefully, a company must organize its flow of documents to ensure that supervisors read, analyze, and respond to bad reports or criticisms written by a company's low-level employee. This is called "closing the loop." Suppose a supervisor, such as an engineering manager, receives a memo from one of his or her subordinates that expresses concerns about the safety or quality of a product. The supervisor must analyze the problem and respond in writ-

ing to that employee. Then, the original memo and the response must be attached or stored together so that if these documents are obtained later in litigation, the original criticism and the response will be considered together. Otherwise, the criticism—without the response—might be discovered, giving the plaintiff the opportunity to portray the manufacturer as willfully disregarding safety by not considering or responding to concerns or criticism.

In summary, writers of company documents should consider the following guidelines when creating documents:

- Assume that what you write will exist forever.
- Assume that your document will be read on national television.
- Avoid creating unnecessary documents, providing copies to the minimum number of people necessary.
- Be careful about documents that blame someone else in the company or describe internal disputes.
- Always "close the loop."
- Do not discuss liability issues except when requested by the company's lawyer.
- Do not speculate, exaggerate, or editorialize.
- Do not make unsupported statements, conclusions, or opinions.
- Write so that you or someone else can understand what you are saying, even years later.
- Use data or facts to support conclusions.
- Do not attempt to be funny or humorous.
- Be careful when discussing product safety issues in financial terms.
- Do not write documents outside your area of expertise or responsibility.
- Avoid using words or expressions, including legal terminology, that are ambiguous or could be misinterpreted, perhaps intentionally, by a plaintiff.

Following these guidelines will not necessarily prevent the creation of potentially harmful documents. That is not the goal. The goal is to avoid generating documents that unnecessarily and incorrectly create an impression that a manufacturer did not sufficiently care about safety.

## The Danger of Not Retaining Documents

Documents that describe a manufacturer's concern for and incorporation of safety into the design of its product are of little litigation value if they are not retained long enough to be introduced in a future lawsuit. In fact, if a manufacturer lacks documents, a plaintiff's attorney might use it against the manufacturer by raising a presumption that the documents were incriminating and that is why they were destroyed.

Suppose, for instance, that during the design phase a product's engineers considered three alternative designs, each with differing levels of cost and safety. In selecting the final design, the company recognized that one of the other two may have been a reasonable alternative design, but it was nevertheless considered and rejected on other grounds.

When the final design is selected, the manufacturer must document and justify why that design was selected and why the resulting product was reasonably safe. The fact that there were safer alternative designs that were rejected does not necessarily mean that the manufacturer would be liable in a subsequent lawsuit. The question is whether it is necessary or useful to keep documents on all three designs.

Some companies might destroy such reports shortly after a product launch because they do not reflect the final design. An extra benefit would be that this would make it more difficult for a plaintiff to argue that the manufacturer should have adopted one of the rejected alternative designs. However, with no documents on which to rely, the company witness will have to describe from memory which alternative designs were considered and rejected, which safety tests were performed during the design of the product to select the final design, and how the company incorporated safety into the final product. Moreover, the company's liability may well rest on the company witness's credibility in front of a jury rather than on the actual facts of the design process. In some situations, it might be better to retain the documents pertaining to the alternative designs that were ultimately rejected.

## A Document Retention System

Establishing an effective, rational, practical, and comprehensive document retention system is not easy. It is impossible within the limits of this article to propose a program that every company can use. Each company must set up a customized schedule that is practical and effective for the amount of documents it creates, the places where they are kept, and the legal and technical requirements for retaining documents.

There are many sources of document retention programs, such as ARMA International, an international records management association, (http://www.arma.org/), and Information Requirements Clearinghouse, (IRCH), also mentioned above, (http://www.irch.com/). The samples offered by these sources can be very helpful to a manufacturer that has not yet established its program. The samples contain extensive lists of the types of documents that a company should keep, where a company should store these documents, how long a company should keep them in the company's offices, and how long a company should retain them after the company moves documents to storage. A company can also classify documents according to importance and easily access a description of the form in which they can be stored. ARMA and IRCH also publish best practices on all aspects of the organization, maintenance, and retention of electronic records.

**Juries and judges** understand that there may be internal differences of opinion during the development of a product.

Each manufacturer must establish its own system and schedules in accordance with its particular needs. One schedule may indicate the method of destruction for certain kinds of documents. A company may need to shred some documents if they could contain trade secrets or other confidential business information. A company may need to burn others, while merely throwing others in the trash. Of course, it is particularly difficult to destroy electronic records. Therefore, schedules need

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to address when to delete certain files on computers, which documents to back up, and which electronic documents to keep forever.

A document retention program should include procedures for periodically moving documents from a company's offices to a storage site or to a backup tape. It should indicate the individual with responsibility for approving moving documents to storage and approving their eventual destruction. A company should also keep a record of what happened to certain documents, when they were destroyed, and who approved the destruction of other documents.

## Product History File

A comprehensive retention program should contain a history of the life of a product, from creation through its end of life. Having a core history, initially assembled after the development of each product or product line, will allow a manufacturer to prove that it complied with all safety and other requirements on a routine basis. The project manager could gather all documents from all sources within a company pertaining to the project and organize them into a comprehensive, coherent file that tells the history of the product. Drafts and duplicates of documents should be destroyed. Documents should be grouped so that an email and its response are attached to each other.

Developing this product history file does not mean that potentially harmful documents, such as an internal memo that questions whether a company should continue developing a particular product, should be destroyed. Juries and judges understand that there may be internal differences of opinion during the development of a product. All a manufacturer will need to explain is how the manufacturer handled this dissenting opinion—that it was fully considered and then accepted or rejected. Disclosure of dissension within a company can actually be beneficial; it confirms that a manufacturer encourages varying opinions and does not try to hide bad or potentially damaging information. Of course, it can also be harmful if a jury believes that a rejected opinion was correct.

There are no specific or universal guidelines on how long a company should keep such documents. A company does need to comply with certain legal requirements. And companies will have an overriding sense of how long to keep documents to support their business purposes. Otherwise, documents that are necessary to explain a product's design should be kept as long as they might be needed to defend the manufacturer. A company will need to make decisions on retention time on a case by case basis, first considering the life expectancy of a product, applicable statutes of limitation and repose, and a prediction of the period of time after the product's life is over that the company might anticipate claims or lawsuits, to name a few.

A manufacturer should keep some documents forever, even if they represent an old design. Subsequent designs and redesigns are often based on earlier designs. Products evolve over time, and therefore, a manufacturer may need the earliest product development documents to explain later designs.

As a result, if developed, a company may need to keep a product history file permanently. Assuming that this file is organized and a company discards duplicates and drafts, the quantity of documents may not be so large that permanent retention becomes a problem. And a company can convert these documents into electronic records so that files subject to future discovery can be easily found.

## Conclusion

In the history of product liability litigation, documents have proven both helpful and harmful to plaintiffs and defendants. However, unfortunately, you will not know until after you create them whether what a client's employee writes today will help or harm your client.

Despite that, a manufacturer must proactively establish a document management system that ensures compliance with legal requirements and results in the creation of a story of the development and life of a product. The system should also include procedures that will minimize the creation of misleading and unnecessarily harmful documents.

Although this system can be difficult to organize and implement, it will clearly confirm a manufacturer's efforts to produce a reasonably safe product and hopefully be helpful in better defending its conduct and products in the future. FD