

Products Liability in the United States Issues for Dutch Companies



NL Agency
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Innovation

Hughes Hubbard & Reed LLP

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I. Introduction

When Dutch business people think of uninviting aspects of the otherwise hospitable U.S. market place, they likely think of America's incredible penchant for products liability litigation. They think of stories they have heard of a lawsuit resulting in a multi-million dollar award for a spilled cup of hot coffee. They think of massive class actions that can result in companies paying billions of dollars. They think of litigation that goes on for decades. What they are thinking of is an area of law known as products liability, which is the litigation of potential safety issues from all kinds of products. Products liability is an important part of doing business in the United States. A company must be realistic about the unique risks it can face from product liability lawsuits in the United States and plan accordingly.

On the other hand, business goes on every day in the United States despite the reality that lawsuits and potentially large verdicts are a fact of life. Dutch companies can appreciate the risk without letting the fear of such lawsuits prevent them from taking advantage of the substantial opportunities that the U.S. market offers.

This booklet is designed to help Dutch companies do just that by putting them on the path to a better understanding of products liability law and providing some guidance on how to limit that liability. The booklet does not attempt to address all issues, and necessarily simplifies those issues it does address. It cannot be taken as a statement of the law in any particular U.S. jurisdiction, and cannot substitute for legal advice from an attorney. But our hope is that there is enough in the pages that follow to help Dutch businesses begin to ask the right questions and better evaluate how to start preparing to do business in the United States.

Section J of Chapter II is primarily based on information obtained from the insurance companies and brokers listed on Chapter VII. We gratefully acknowledge their assistance.

II. The Basics

A. What is products liability?

- *Products liability is the area of law governing injuries caused by products.*

The fruits of manufacturing – drugs, machines, cars, computers, toys, beds, food, and so on – are known in the law as products. When a person is injured as the result of using a product, he or she may sue to recover money to compensate for the injury. This area of law is known as products liability.

Products liability is an important area of law in the U.S. and a crucial area to understand for anyone doing business there. Although much of Europe has products liability law that shares much in common with U.S. products liability law, certain key differences like juries, high damage awards and contingency fees can make U.S. products liability law intimidating for Dutch companies. Many Dutch business people have heard stories of lawsuits that result in companies having to pay multi-million dollar awards for seemingly trivial injuries. Some of these stories are true, but companies can do many things to limit their risk.

- *Products/service distinction*

Products liability law applies to lawsuits alleging that a product caused an injury. Businesses that are principally providing services are not subject to strict liability under products liability law. For instance, hospitals and doctors are not subject to strict liability law for a defective drug or device used in the treatment of a patient. It is a service that the hospital and doctor are providing. They can only be liable if they did not exercise the level of care of a reasonable hospital or physician. This is called negligence. Strict liability means that the manufacturer is liable for injuries caused by a defective product regardless of whether the defect was the result of negligence.

B. For what reasons can a company be sued in products liability?

When a defective product causes harm, the injured person may have a right to sue. There are three kinds of defect: manufacturing defects, design defects and failure to warn. An injured person may also sue a company on the theory that the company's negligence caused the injury.

- *Manufacturing defect*

A defect in a product that is the result of faulty manufacturing is called a manufacturing defect. An example of a manufacturing defect is, if a manufacturer produces drugs and inadvertently contaminates a batch of the drug with a toxic foreign substance.

- *Design defect*

A defect in the design of a product is called a design defect. As explained below, there are a number of different tests for what counts as a defective design. In general, fault or lack of care in designing the product is not important in determining whether a product has a design defect. The manufacturer is expected to design out of the product all of the safety risk that it is feasible to eliminate by design. For example, if a car is designed with a bolt right behind the gas tank so that if the car is struck from behind the bolt will penetrate the gas tank and cause an explosion: that is a design defect.

- *Failure to warn*

A product manufacturer has the legal duty in the U.S. to provide a warning regarding all risks of injury associated with the foreseeable use and misuse of the product. Some risks are inherent in

the design of certain products. Such a product can be made nondefective from a legal point of view by providing an adequate warning. For instance, most drugs have side effects. No amount of care in the design or manufacture of drugs will change that. If, however, consumers are given adequate warnings about the side effects, the product will not be considered defective.

Products liability is not the only theory under which a company may be sued. Some other theories are listed below.

- *Negligence*

An injured person may also sue a company on the theory that the company's negligence caused the injury. Negligence is the failure to follow the ordinary standard of care that a "reasonable" person or company would follow in safeguarding product users from injury.

- *Express/Implied Warranty*

A warranty is a promise that a fact is true. It is a term of the contract to buy a product. Express warranties may be contained in literature that accompanies the product or statements made by the manufacturer's marketing and sales force. Implied warranties are promises the law implies as part of every contract. Essentially, the court acts as if every manufacturer promises two distinct things. First, there is an implied promise that a product will do what it was made to do – a knife will cut, an oven will cook and so on. Second, there is an implied promise that a product will meet certain ordinary purposes for such good. This broader promise is called the warranty of merchantability and includes the idea that a product would not be unreasonably safe. The whole field of products liability law grew out of this original idea that every sale involves a promise that the good being purchased would be reasonably safe. Today, many states have eliminated the idea of this implied warranty and replaced it with statutes that spell out products liability law. However, the concept still exists in some states. Whether the lawsuit is brought under this notion of an implied warranty of merchantability or under a statute, the plaintiff still must allege that the product was defective in one of the three ways listed above.

- *Consumer Fraud*

There has been a recent trend to sue under various state consumer protection statutes. These statutes make it unlawful to engage in unfair or deceptive acts or practices in the conduct of trade or commerce. Plaintiffs have used these statutes to bring class actions claiming that a product was deceptively marketed in violation of the statute either because it was affirmatively marketed as safe when it had an allegedly undisclosed risk or the marketing omitted risk information that misled consumers into believing the product was safer than it actually was. Some statutes lower the traditional requirements of "fraud," allowing plaintiffs to bring claims even where they cannot prove an intentional deception or that the plaintiff relied on false representations from the manufacturer. These consumer fraud claims typically seek only the return of the purchase price. For this reason they are pursued collectively for all purchasers in the form of class actions. These claims are easy to allege but difficult to prove. A full discussion of the consumer protection statutes of all 50 states is beyond the scope of this booklet.

- *Magnuson-Moss Warranty Act*

The Magnuson-Moss Warranty Act is a federal statute. Federal statutes are laws of the government of the United States, as opposed to most of the laws we are discussing, which are laws of one of the fifty individual states. The Act imposes certain requirements on a manufacturer who issues a full warranty for its product. In general, these requirements are designed to prevent any attempt by the manufacturer to use express warranties to restrict its liability to consumers unless the warranty is written in a way that is clear to regular consumers and makes the restriction of liability apparent on its face. For instance, it forbids the limitation of consequential damages for breach of an express or implied warranty unless the limitation conspicuously appears on the face of the warranty. A full discussion of the Magnuson-Moss Warranty Act is beyond the scope of this booklet.

- *Medical Monitoring*

Some jurisdictions permit persons who have been exposed to a product, but have suffered no physical injury, to sue for “medical monitoring” for injuries which may develop. Most such theories of medical monitoring are based on the decision *Bower v. Westinghouse Elec. Corp.*, 206 W. Va. 133, 206 W. Va. 133 (1999). Under *Bower*, a plaintiff must prove that:

- (1) he or she has been significantly exposed;
- (2) to a proven hazardous substance;
- (3) through the tortious conduct of the defendant;
- (4) as a proximate result of the exposure, plaintiff has suffered an increased risk of contracting a serious latent disease relative to the general population;
- (5) the increased risk of disease makes it reasonably necessary for the plaintiff to undergo periodic diagnostic medical examinations different from what would be prescribed in the absence of the exposure; and
- (6) monitoring procedures exist that make the early detection of a disease possible.

Medical monitoring claims are being brought increasingly in circumstances where there is (1) some unfavorable scientific evidence that a product poses a risk to human health (often just in animal studies) but the question is unsettled and (2) where the injuries themselves, like cancer, may take years to manifest. Plaintiffs typically claim in such circumstances that their exposure to the product entitles them to money for doctor visits and testing to catch early any developing, product-related injuries. Depending in large part on the jurisdiction in which the case is brought, medical monitoring claims often can be defeated through aggressive discovery and sound legal argument.

C. Who can sue for a products liability claim?

- *The injured product user*

The person who used the product and suffered an injury has the right to sue.

- *The injured bystander*

A product may be alleged to have injured not the user but some innocent bystander, as when a car runs a red light and hits a pedestrian because of faulty brakes. The pedestrian can sue the car manufacturer even though he did not purchase the car.

- *The spouse*

The husband or wife of the injured product user can also sue for the harm he or she suffered as the result of having an injured spouse. The spouse sues for his or her loss of consortium, meaning the loss of the injured spouse’s normal support, love and sexual relations.

- *The children*

In most states, the children of the injured product user can also sue for the harm they suffered as a result of having an injured parent. Parents are expected to provide emotional support to children. Children can claim that they have been damaged in losing this support.

- *The estate*

When a product user dies as the result of using a product, the estate of that person can sue. The estate can seek recovery for the income that the deceased would have earned if not for his untimely death, for the deceased’s pain and suffering prior to death, for the deceased medical expenses, and, in some states, the funeral expenses.

D. Who can be sued in products liability?

- *Anyone in the chain of distribution*

Everyone in the chain of distribution can be sued for the full amount of damages; from the manufacturer, to the retailer who sold the product, to the end user. This rule was meant to protect injured parties by allowing the plaintiff to sue the person who sold him the product and put the burden on those defendants to find the ultimate manufacturer.

- *Parent companies, sometimes*

A parent of a subsidiary that sells or manufactures a product cannot be sued in products liability for suits arising from the use of the subsidiary's products. However, if the plaintiff can show that the parent and subsidiary are really a single business entity, or that the parent played a role in the design, manufacture, or marketing of the product, then the plaintiff sometimes can proceed against the parent.

- *Ultimately, the wrongdoer is to pay*

However, just because the product distributor and retailer can usually be sued does not mean that they are ultimately responsible even though they may end up paying some or all of the damages. Ultimately, it is only the wrongdoer, the party that caused the injury, that is responsible.

- *Indemnification*

Indemnification is the legal right of retailers and distributors to make the manufacturer pay for any damage the defective product caused. In other words, if a customer claims to be injured by a product and sues the retailer who sold it to him, the retailer can in turn sue the manufacturer and recover whatever damages the retailer has had to pay.

- *Contribution*

The defendant has a claim for contribution against other parties who may have contributed to the injury. For example, suppose a consumer sues a tire manufacturer claiming that she was injured when her car overturned as the result of a tire blowout. The tire manufacturer claims that the car was defectively designed because a blowout at the speed the plaintiff was driving should not have resulted in a loss of control of the car. On this theory, that the car's defective design was partly responsible for the injuries, the tire manufacturer can sue the car manufacturer for contribution. A jury will then have to decide what portion of the plaintiff's injuries was due to the defective tire and what portion was due to the defective design of the car. In many jurisdictions settlement extinguishes the right of contribution.

- *Joint and several liability*

The rule of joint and several liability holds that the plaintiff can get the full award of his damages from any defendant found liable. In other words, suppose a plaintiff who is injured in a car crash sues the drunk driver who caused the accident as well as the car manufacturer claiming his injuries were made worse by defective brakes. If the jury returns a \$1 million verdict finding that the drunk driver was 90% responsible for the accident and the car manufacturer was 10% responsible, under joint and several liability the plaintiff can recover the total amount from the manufacturer. The manufacturer then has the right to attempt to recover 90% from the drunk driver. Many states have eliminated joint and several liability in some situations, such as where the defendant is less than 50% at fault.

E. Where can a Dutch company be sued?

- *The plaintiff can bring a suit in any court he chooses; however, the suit may be dismissed or moved to another court depending on a number of factors.*
- *Jurisdiction*

Jurisdiction is the right of a court to hear a claim. Just because a plaintiff has sued in a particular court does not mean that the court has the right to consider the case. Generally, if a Dutch company plans to have its products enter the U.S. market as a whole or a particular state's market and those products cause injuries in that state, then the courts of that state will have jurisdiction to hear the case. However, a product that merely ends up in a state without any such plan is usually not enough to give the courts of that state power over the Dutch company.

- *Venue*

Venue is the place within a jurisdiction where a suit is filed. Courts have rules to determine if a venue is appropriate. Often in products liability cases the choice of venue is as critical as any decision made in the case. The enormous verdicts that make headlines and generate concern are frequently the product of a handful of courts that are viewed as plaintiff friendly. In some instances, plaintiffs improperly bring their cases in these courts. Since choice of venue may have a large effect on the ultimate outcome of the lawsuit, it is important to carefully check rules of venue to see whether venue chosen by plaintiff is appropriate.

- *Forum non conveniens*

Forum non conveniens means inconvenient forum. It is an important legal doctrine that, depending on the facts at hand, may provide a foreign company with a theory to seek dismissal of a lawsuit. Where the evidence and witnesses are not available in the state where the case will be tried and cannot be brought there without considerable expense, a court can dismiss for forum non conveniens. For example, a court could decide that the matter should be litigated in the Netherlands instead of the U.S.

- *Removal jurisdiction*

Another important means by which a defendant may sometimes seek a more favorable forum is through a procedural device called removal. In the U.S., each state has its own courts. In addition, there is a system of federal courts. In some circumstances, a defendant who has been sued in a state court can have the case removed to federal court. Often federal courts are preferable to state courts. Defendants may feel that state court judges are overly sympathetic to plaintiff's attorneys. Also, state court rules of procedure or evidence may be unfavorable. One particularly important example discussed below is the typically higher standard federal courts apply to scientific evidence before allowing it to be presented to a jury.

F. What law will be applied to a Dutch company?

- *The law of the state where the alleged injury occurred, generally, will apply in products liability cases; however, there are complications.*

In the United States, there is no national law that covers products liability. Each state has its own law. Even if a case is tried in a federal court, the law of a particular state must be applied. Often, slight differences in the law between states can change the outcome of a case. Commonly, the law of the state where the injury occurred governs.

G. What sort of damages may a company have to pay if found liable?

- *Compensatory damages*

Compensatory damages cover items like income lost because of the injury, reasonable healthcare costs, the cost of medical monitoring for future health problems related to the injury, past pain and suffering, and emotional distress. Dutch companies should be aware that damages for these items are generally substantially higher than the damages awarded by Dutch courts in similar matters. It is not rare for damage awards to be in the million dollar range for cases involving death and serious bodily injury.

- *Punitive damages*

Punitive damages are meant to punish the defendant and provide a deterrent for future wrongful behavior. The enormous jury awards that have been reported in the media are often punitive damage awards. In many states, the plaintiff must prove malice, i.e., ill will, to receive punitive damages. There has been a recent trend in the courts to roll back excessive punitive damages awards.

- *Collateral source rule*

Many states have a rule called the collateral source rule. Under this rule, evidence that a plaintiff has already been compensated for his injuries by a third party like an insurance company, cannot be admitted as evidence and the plaintiff's damage award cannot be reduced to offset the amount he already received. Under the collateral source rule, the manufacturer defendant cannot put in evidence the fact that plaintiff received compensation already from his insurance. The defendant will have to pay the plaintiff the full amount. However, the plaintiff's insurer may have a right to recover from the damage award. For example, a plaintiff's medical expenses may have been paid for by his insurance.

- *How much can be awarded?*

The question of how much to award is usually decided by juries. Under U.S. law, the question of how much money will compensate the injured party is a question of fact. Juries decide questions of fact. A jury's determination of compensatory damages receives a great deal of deference from the trial judge and the appellate courts, making it less likely that these awards can be overturned. Because compensatory damages involve subjective questions like the monetary value of pain and suffering, these awards can be quite large.

Punitive damages, on the other hand, are a question of law. The jury still determines the amount of punitive damages, but because of a recent series of Supreme Court decisions, courts must now review these awards more carefully and make sure that they are in reasonable proportion to the compensatory damage award.

There have been a number of reform efforts to rein in large damages awards. However, compared to the Netherlands, damages awards are still very high. Multi-million dollar awards are not unusual. Although many cases result in substantially smaller verdicts and settlements, the chance of "hitting it big with a jury" is a major incentive for consumers and plaintiff's attorneys to bring products liability lawsuits.

- *Is there any way to lower an excessively high damage award?*

Yes. A trial court or an appellate court can lower the amount the jury awarded. As mentioned above, the Supreme Court of the United States has ruled that punitive damage awards must be in reasonable proportion to the compensatory damages award. Although not entirely clear, it seems that any award for punitive damages that is more than ten times the size of the compensatory damage award will be found unreasonably high.

Trial judges and appellate courts usually have less discretion to reduce compensatory damage awards. But, there are a variety of ways to seek to have a compensatory damage award overturned or reduced.

H. What else is different about the U.S. judicial system?

- *Contingency fees*

In the United States, attorneys working for plaintiffs in product liability typically work on a contingency fee. Plaintiffs do not pay the attorney anything unless they receive an award or settlement; then they pay a percentage – usually 20% to 40% – to their attorney. In the Netherlands, this arrangement is sometimes referred to as a “no cure, no pay” arrangement.

- *Loser does not pay*

In the United States, unlike in the Netherlands, a plaintiff who brings a lawsuit and loses will not have to bear any of the costs of the defendant.

- *Jury*

In the United States, juries decide issues of fact, which are most of the issues in a lawsuit. Juries are composed of ordinary citizens. The size of juries can range from six to twelve members depending on the jurisdiction. The process of selecting juries also varies, but generally there is a process called voir dire which permits the parties to weed out jurors who are biased. In addition, in some courts the parties may have a limited right to eliminate a few jurors without having to show the juror had any bias.

- *Discovery*

The discovery process is an important part of litigation in the U.S. and one that Dutch companies probably find most surprising. Once a lawsuit is started, each party may ask the other for any information (witnesses, documents, e-mails, etc.) that may be relevant to the lawsuit and the other party is required to produce it. There are some limits to what a party may request, but the inclination of the judicial system in the U.S. is for full disclosure.

In many lawsuits the parties can work out agreements about what each side reasonably needs in order to pursue the lawsuit. However, in products liability suits discovery can become very burdensome to the defendant. Since the plaintiff is an individual with few, if any, documents or information to disclose, he can seek massive discovery without fear of being subjected by the defendant to the same burden. Discovery of all of the documents, emails and employees involved with a particular product can be enormously costly. Therefore, preparing to meet the challenge of discovery is one of the first steps a company must take after being sued. In fact, it must begin to prepare before any suit has been filed.

- *Class Actions*

In the U.S., a person who purports to represent a whole class of persons who have been injured in the same way can bring a lawsuit on their behalf. This procedure, called a class action lawsuit, allows one individual or a small group to represent thousands or even millions of individuals. Before a class action may proceed, the plaintiff must meet a rather rigorous test.

Class actions are particularly frightening to defendants because one verdict for a large class could result in damage awards of up to billions of dollars.

- *Consolidations and coordinations*

Claims of multiple plaintiffs can be brought in a single lawsuit or different lawsuits can be joined into a single lawsuit. This is sometimes called consolidation. Like a class action, in such a consolidated action there will be a single trial for the all of the claims. Defendants may oppose such consolidations because there are fundamental differences between each plaintiff's claims.

In addition to consolidation, there are procedures in state and federal courts that permit the coordination of claims. Coordination procedures deal mainly with procedural aspects like discovery, evidence and various other motions. In the federal courts of the U.S., cases are coordinated in what is called a Multi-District Litigation court. This court handles all discovery and motions filed before trial. Then, the cases are returned to the courts where they were originally filed. In coordinated actions unlike class actions or consolidated actions, each lawsuit is treated separately for the ultimate determination at trial.

Consolidations are designed to lower the expense of litigation. However, the practical effect is often to make it cheaper and more profitable for plaintiffs and their attorneys to bring suits. This, in turn, encourages even more litigation. There may be circumstances in which a defendant wants to have its litigation over a single product consolidated. However, this decision should be carefully considered.

III. **How Can a Dutch Company Limit Its Risk?**

To limit a company's exposure to products liability suits in the U.S., a Dutch company must develop a plan that is aimed to address real safety concerns and also to prepare the company for litigation. In addition, a Dutch company should engage an insurance broker to obtain adequate insurance coverage.

A. **Product safety review**

The central feature of a product review safety program is a review that focuses on those aspects of a company's operations that are most likely to affect the safety of its products. These include:

- (1) The visible commitment of management to product safety;
- (2) The process by which the company's products are designed;
- (3) The company's and its suppliers' manufacturing quality control programs;
- (4) The adequacy of the company's product warnings and instructions;
- (5) The adequacy of the company's accident reporting and investigation procedures;
- (6) The consistency of the company's product advertising promotion with its products' performance and the warnings given by the company; and
- (7) The adequacy of its document control and retention policies.

The following discussion summarizes the legal background underlying each of these topics and includes a suggested safety review (including appropriate checklists) that can be modified to meet the needs of a particular product or company. The purpose of the review is not to "pass" or "fail" a particular product or to certify that it will survive an attack in a product liability lawsuit. Rather, the emphasis is on the process by which safety concerns are addressed. The goal is to provide a framework for improving that process.

B. **Management commitment**

Legal background. In applying the modern-day remedy of strict products liability, courts often give lip service to the principle that strict liability focuses on the condition of the product not the conduct or fault of its manufacturer. Those who follow developments in the law of products liability know that this simple notion does not accurately reflect the extent to which fault and negligence principles still permeate many, if not most, products liability cases, including those based on strict liability. A plaintiff's attorney rarely will forego the opportunity to put a manufacturer and its management on trial, particularly when it is alleged that the product was not properly designed, or that the risk of harm was not adequately warned about, or when the plaintiff is seeking punitive damages. Fault as a basis for liability appeals to jurors, and a plaintiff is more likely to recover a substantial award if he can establish fault or a disregard of safety at the highest levels in the company.

Visibility of management commitment. For this reason, an important aspect of any product safety program is a visible and well-documented commitment by management to promote product safety and to adopt company-wide, safety-related policies and procedures. A good way to achieve this goal is for management to distribute a policy statement to all employees that sets forth: the company's commitment to manufacture products that are safe and reliable; the name(s) of the person or persons responsible for implementing the policy; and the manner in which it will implemented.

Safety officer or safety committee. The policy statement usually designates a high company official to be responsible for product safety. In larger companies it often may also designate a product safety committee made up of representatives from management, engineering, manufacturing, sales, advertising, service, quality control, insurance, and legal. The policy statement should not commit to more than is realistically attainable since the failure to follow through on a commitment can be used against a manufacturer in a product liability case. Similarly, it is important that the product safety officer or committee have authority to make major decisions or at least to make recommendations directly to top management. Nothing can be more devastating in a product liability case than proof that the plaintiff's injuries were caused by a product problem that resulted from a failure to follow a reasonable safety recommendation.

The product safety officer or committee also should have safety-related authority to:

- (1) Review product designs and the design process;
- (2) Review product quality control procedures and practices;
- (3) Review product warnings, instructions and labels;
- (4) Review product warranties, disclaimers of warranties, indemnities, and related documents and consult with company counsel in connection with these items;
- (5) Review accident and warranty reports, and other data for evidence of safety-related problems;
- (6) Review advertising and promotional material for accuracy and consistency with product warnings and instructions, and with product performance;
- (7) Review document retention programs to ensure the retention of documents that are needed to defend products liability actions;
- (8) Conduct or supervise product safety reviews and audits to determine whether the company's policies and procedures are being carried out; and
- (9) Develop programs and seminars to educate company personnel about product liability issues and developments.

Management commitment checklist. The review of management's visible commitment to product safety should include the following topics:

- (1) *Policy statement.* Has management distributed to all employees a product safety policy statement? Does the policy statement accurately describe the manner in which the company's safety function is organized?
- (2) *Safety officer or committee.* Has the company designated a product safety officer or safety committee?
 - (a) Are the functions and responsibilities of the product safety officer or committee spelled out in sufficient detail?
 - (b) Has the product safety officer/committee been integrated into the company's decision making process so that the officer or committee has access to the company's activities that can affect product safety as well as to its top management?

- (c) Does the product safety officer/committee maintain adequate records that demonstrate responsiveness to safety concerns, willingness of the company to follow safety recommendations, and thoughtful consideration of all safety recommendations, including those that are rejected by the product safety officer/committee?

C. Product design process

Legal background. Products liability law imposes liability on a manufacturer for injuries caused by defects in the design of its products. In a design defect case, the injured plaintiff does not claim the product that injured him differed in any way from units of the same product sold by the manufacturer to others. Typically, the manufacturer is charged not with inadvertently producing a flawed product, but with intentionally selecting a defective design. These cases can be particularly dangerous to a manufacturer since the finding of a defect can mean condemnation of the entire product line.

Under either the consumer expectation test or the risk-benefit test (which are described below), the courts usually will look at a broad range of factors in a design defect case including: government regulations and standards; industry standards and custom; the state of the art; alternative designs; the utility, benefits, costs, risks, and effectiveness of the chosen design and the needs, expectations and sophistication of the users of the product; special risks created by the environment in which the product is used; the manufacturer's internal design, marketing, and management documents; advertising materials; patent applications; lobbying activities with respect to government standards, rules and regulations; cost-benefit analysis; evidence of similar accidents; evidence of the absence of similar accidents; reports of government safety agencies; evidence of tests and experiments and the availability of safety devices.

Design process. An ideal design process is one in which all the significant hazards inherent in the uses and foreseeable misuses of the product have been identified and either designed out of the product or made the subject of a project warning.

Whether a product has been designed to meet this goal is a question that involves mainly engineering and technical rather than legal judgments, and it is not the purpose of the proposed review to challenge the design of any product. Rather, the proposed review will focus on whether the design process took into account the principal factors a court would look at in determining whether a product is unreasonably dangerous because of its design.

Design process review checklist. With those goals in mind, the review should seek to determine whether the following items were covered in the design process;

- (1) *The customer or user.* Who is the ultimate customer or user of the product and what are his:
 - (a) needs;
 - (b) safety expectations;
 - (c) uses of the product; and
 - (d) foreseeable misuses of the product — is the customer a sophisticated user and are the customer's employees sophisticated users?
- (2) *Environment of use.* Has the environment in which the product is to be used been identified?

- (3) *Hazard identification.* Has the company attempted to identify and to characterize, in terms of severity, the hazards arising from the uses and foreseeable misuses of the product (including hazards in packaging, transporting and disposing of the product after use) within its environment of use or has it relied on the hazards identified by a third party?
- (a) If the company has performed its own hazards identification, has a record of that analysis been retained; was the analysis performed in accordance with such formal analytical techniques as Hazards Analysis, Failure Mode and Effects Analysis, or Fault Tree Analysis; and has the analysis been updated in light of scientific advances and the accident/litigation history of the product?
 - (b) If the company has relied on the hazards identified by third parties, has a record of that analysis been retained and has it been updated in light of scientific advances and the accident/litigation history of the products?
 - (c) Is the hazard open, obvious and commonly known?
 - (d) Has the company documented the steps it has taken (e.g., design modifications, warnings, etc.) to minimize the identified hazards?
- (4) *Applicable regulations and standards.* Has the product been designed to comply with (or exceed) all applicable federal, state and local codes and regulations, industry standards and customs, and the company's own design standards and criteria? Have these codes, regulations, standards and customs been identified and does the company update them in light of current developments?
- (5) *Earlier designs.* Were earlier versions of the same product and their hazards identified and analyzed?
- (6) *Alternative designs.* Were alternative designs or approaches identified and analyzed in terms of utility, cost, safety, and feasibility?
- (7) *State of the art.* Was the product designed to a recognized state-of-the-art standard?
- (8) *Testing.* Was the product tested at appropriate stages in the design process?
- (9) *Design reviews.* Was the product design subjected to preliminary, intermediate and final design reviews that affected its safety characteristics?
- (10) *Risk reduction measures.* If the hazard cannot be designed out of the product, has the company considered additional safety precautions or devices such as guards, warning lights, automatic cut-off switches, or protective cages that will reduce the risk of harm?
- (11) *Safety Devices.* Does the company sell any safety devices as optional equipment?
- (a) Has consideration been given to making the optional equipment standard?
 - (b) Does the company maintain records that establish that the optional equipment was recommended by the company and was unequivocally rejected by the customer, who was fully informed of the risks of using the product without the safety device?

D. Manufacturing process

Legal background. A product manufacturer can be liable for injuries caused by a defect or flaw in the manufacture of the product.

A manufacturing defect is determined by comparing the product as manufactured with the manufacturer's own designs and specifications. If the plaintiff is injured because the product did not comply with these designs and specification, the manufacturer is strictly liable, regardless of the degree of care it exercised in making the product.

The key to avoiding liability for manufacturing defects is to establish and maintain a reliable quality control program. Not only will such a program increase the probability that the product is manufactured in accordance with the manufacturer's designs and standards, but evidence of the program ordinarily will be admissible to show the improbability that the product was defective when it left the manufacturer's possession and the probability that the alleged defect was introduced in the post-manufacturing stage of the product's life cycle.

Quality control checklist. Because the adequacy of a quality control program largely involves technical and engineering judgments rather than legal judgments, the quality control inquiry is limited to the following topics:

- (1) *Documented program.* Can the company establish by documentary evidence that it has a quality control program which is consistent with sound engineering principles and with programs generally used in its industry, and that it follows this program?
- (2) *Reclaiming product.* Do procedures exist for stopping the production line and for reclaiming the product from the channels of distribution when a manufacturing defect is discovered?
- (3) *Suppliers.* Does the quality control program focus not only on in-house production, but also on products bought from suppliers of raw materials and components?
 - (a) Do procedures exist for inspecting and rejecting inferior material from suppliers?
 - (b) Do purchase orders and sales contracts contain warranties, hold harmless and indemnification provisions sufficient to protect the company from liability for defects in its suppliers' products?
 - (c) Does the company routinely sign purchase orders from its suppliers without reviewing the usual terms of sale provisions printed on the documentation or does it refer these provisions to counsel or seek to renegotiate these terms?
 - (d) Have suppliers provided proof of adequate insurance and have they named the company as an additional insured? Are suppliers' certificates of insurance and the vendor's endorsement reviewed?
- (4) *Procedure — inspections and tests.* Are procedures (including inspections and tests) in place to insure that products are manufactured according to relevant specifications?
 - (a) Are records kept that reflect the carrying out of the required inspections and tests?
 - (b) Are service, warranty and field reports routinely reviewed for evidence of quality control problems?

- (5) *Deviations.* Is the authority to deviate from design specifications clearly spelled out in writing and are all such deviations fully documented?

E. Warnings and instructions

Legal background. Product liability law imposes on the product manufacturer a duty to warn of risks inherent in its product if the manufacturer knew or should have known of these risks. In a few cases, the courts have suggested that the duty to warn is so strict that it includes a duty to warn of risks that were unknown and scientifically unknowable at the time the product was manufactured.

Many courts recognize that a product manufacturer has no duty to warn a user of the product who is fully aware of its danger. This “knowledgeable user exception” is usually applied to professionals or those with special knowledge, training, experience, or expertise. The exception does not apply to laypersons with limited familiarity with the product. The user’s knowledge must be specific, not general, and equal to that of the manufacturer. Also, there is a risk that a court would not apply the knowledgeable user exception if the purchaser of a company’s product is a knowledgeable purchaser but its employees, who actually use the product, are unskilled workers who have no specific familiarity with the product.

Some, but not all, courts relieve a manufacturer of a duty to warn when the risk or danger is open, obvious or commonly known. Also, a manufacturer has no duty to warn the product user of inconsequential risks, particularly if the injury can only arise from idiosyncratic reactions to the product.

The duty to warn extends to risks created by intended uses as well as foreseeable misuses of the product. Many courts have vested the product manufacturer with the powers of a clairvoyant in determining whether a misuse of its product was foreseeable. The duty to warn also extends beyond the immediate purchaser of the product to third parties who are foreseeable users (and misusers) of the product. It may also extend to the employees and customers of the purchaser, particularly when the manufacturer has effective means of communicating the warning to the ultimate user of the product and has reason to believe that its immediate customer will not pass on the warning to the ultimate user. For example, some courts have held that manufacturers of bulk chemicals can be liable for failure to warn the ultimate user of their product when the manufacturer’s customers have repackaged the product in smaller containers without including a warning similar to that supplied by the manufacturer.

In deciding whether a warning passes muster under the law of product liability, the courts have looked at the following factors:

- (1) Is the warning intense enough to convey the gravity of the harm?
- (2) Does one part of the warning dilute another part?
- (3) Has the warning been communicated in a manner designed to reach the person to whom it is directed? If possible, has the warning been permanently affixed to the product and if there is reason to believe that the users do not read English or are illiterate, has the warning been expressed in multiple languages or by pictures and symbols?
- (4) Do the product’s physical characteristics lull a user into a false sense that the product is safe (e.g., if a poisonous, colorless liquid is contained in a clear bottle so that the product looks like water, it may create a risk of injury under some circumstances that cannot be overcome by any written or symbolic warning)?
- (5) Is the warning nullified by overpromotion of the safety aspects of the product or is it undercut by advertising or promotional material?

- (6) Is the warning clear, specific, unambiguous and conspicuous?
- (7) Does the warning list remedies or antidotes for adverse reactions?

Moreover, in some cases, an adequate warning of the risks inherent in the use of the product may not be sufficient in the absence of instructions for the safe use of the product.

The content of the warning may be prescribed by federal or state law which may set only a minimum standard that may not satisfy the requirements of the applicable products liability law.

Proposed review of warnings. The review of product warnings may be the most important aspect of the proposed safety review program. Cases based on a failure to warn are becoming increasingly popular with plaintiff's lawyers, and it has been estimated that eighty percent of plaintiff's recoveries in the future will result from inadequate warnings.

The drafting of a legally sufficient warning often is a difficult task that requires a knowledge of the applicable case law and statutory authorities and a practical, common sense understanding of the needs of the product seller, customer, and user. For example, if the warning is too draconian, it may undermine the commercial viability of the product or be construed as an admission that the product is defective or dangerous. But if the warning is too weak, it may fail to influence the behavior of the user, and the seller may find itself without a defense in a products liability case.

Warnings and instructions checklist. The review of warnings should cover the following topics:

- (1) *The customer or user.* Who is the ultimate customer or user of the product and what are his needs, safety expectations, uses of the product, and foreseeable misuses of the product? Are the customers and his employees sophisticated users?
- (2) *Environment of use.* Has the environment in which the product is to be used been identified?
- (3) *Hazard identification.* Have the hazards inherent in the uses and foreseeable misuses of the product been identified and characterized in terms of severity, and are some or all of these hazards open, obvious and commonly known?
- (4) *Hazard reduction.* Have the hazards been reduced to the extent practicable through the design of the product?
- (5) *Description of hazard.* Does the warning adequately describe the nature of the risk:
 - (a) Is the warning sufficiently intense to describe the severity of the danger, i.e., is the intensity level (DANGER! — WARNING! — CAUTION!) appropriate for the possible consequences?
 - (b) Does the warning describe, with adequate specificity, the nature of the risk so that the user knows what consequences to expect if he fails to heed the warning (e.g., "will cause death or serious bodily injury," "will cause severe eye burns," etc.)?
 - (c) Is the warning internally consistent?
 - (d) Are there special risks concerning the disposal of the product or its packaging that the customer should be warned about?

- (e) Does the warning label “overload” the senses with descriptions of trivial or far-fetched risks?
 - (f) Is the description of the risk undercut by product promotional literature and advertising, and should the warning be included in such materials?
- (6) *Avoidance of hazard.* Does the warning sufficiently describe how to avoid the risk (e.g., “turn off all pilot lights,” “wear safety glasses,” etc.)?
- (7) *Location of warning.* Is the warning permanently affixed to the product or its container to the extent practicable? If the customer transfers the product to another container, has the customer been supplied with warning labels for the new container?
- (8) *Conspicuousness.* Does the warning stand out from other written matter on the label (e.g., highlighted, in bold capitals, in a bright color, etc.)?
- (9) *Intermediate handlers of product.* If the product changes form, is combined with other products, or is repackaged between the time it leaves the manufacturer’s possession and the time it is used by the ultimate consumer, is the original warning still appropriate, is it passed on by the intermediate handlers of the product, and, if not, is there a feasible way that it could be passed on?
- (a) If it is not feasible for the manufacturer to give the warning directly to the ultimate user, is the warning given to the person in the best position to convey the warning to the ultimate user?
- (10) *Government regulations and private standards.* Is the warning in compliance with government labeling and other requirements and with industry labeling standards?
- (11) *Multiple languages and symbols.* Are there characteristics of the product or its users that dictate the use of multiple languages or pictorial or symbolic warnings (e.g., skull and cross bones) or changes in the physical characteristics of the product to make the danger more obvious (e.g., adding an odorizer or dye to the product)?
- (12) *Instructions.* Are instructions for the safe use of the product provided to customers and users of the product?
- (a) Do these instructions repeat the warnings?
 - (b) Are the warnings cross-referenced to the instructions?
- (13) *Antidote.* Does (should) the warning describe an antidote for those who do not heed the warning?
- (14) *Updating.* Is the warning updated periodically in light of new scientific information, changes in the product, and other developments? Is the process by which updating is considered documented?
- (15) *Competitor’s warnings.* Do others who manufacture or sell the same product (including the company’s subsidiaries) provide more extensive or (arguably) better warnings and instructions?
- (16) *Reviews.* Are warnings and instructions reviewed by engineering, marketing, and legal personnel?

- (17) *Litigation history.* Has a similar warning been upheld or criticized by a court?
- (18) *Records.* Are records of the labeling history of the product maintained, including the reasons for rejecting more stringent warnings?

F. **Post-sale phase**

Legal background. Products liability and statutory law impose on product manufacturers certain post-sale obligations to issue new or revised warnings or to recall a defective product.

A post-sale duty to warn may arise: (1) when a danger that was unknown at the time of sale is discovered at a later time; or (2) when a misuse of a product that was unforeseeable at the time the product was sold becomes known and thus foreseeable at a later time. Also, at least one court has suggested that under certain circumstances a manufacturer may have a duty to notify customers of safety-related changes in the state of the art, such as the development of a more effective safety device for the product.

A product manufacturer who discovers post-sale that it has sold a defective product may not be able to absolve itself from future liability by issuing a warning. It may also be required to offer free repairs, to communicate that offer in time to prevent an accident, and to warn of the risks and dangers involved in using the unrepaired product.

Special rules created by statutes govern the recall of some products, such as consumer products, drugs, motor vehicles, and boats.

Plaintiffs in product liability actions often will pursue evidence of post-sale accidents. Also, evidence of the absence of such accidents can be extremely helpful in defending against allegations that the product is defective.

Post-sale obligations checklist. The review of post-sale procedures should consider the following areas:

- (1) *Monitoring.* Are warranty claims, lawsuits, service and maintenance reports, customer complaints, and government and industry statistics and literature monitored for evidence of possible product defects?
- (2) *Accident reporting and investigation.* Has the company established satisfactory accident reporting and investigation procedures?
 - (a) Is the company's accident reporting and investigating procedure designed to insure that the absence of any evidence of a similar accident can be established in a product liability action in accordance with the strict rules of evidence?
 - (b) Are all the reports of accidents involving the company's product investigated to determine whether they are, in fact, similar and whether they are caused by a defect or hazard in the product or by some other cause not related to the condition of the product at the time it was distributed?
- (3) *Post-sale procedures.* Has the company established procedures for determining whether the discovery of post-sale product safety problems should or must be the subject of a warning or a mandatory or voluntary recall program?

- (4) Does the company have procedures for making available to past purchasers of the product any new safety features that were developed after the product was sold? Would it be feasible to do so?
- (5) *Governmental reports.* Do accidents and the discovery of safety-related defects have to be reported to any governmental agency? If so, have they been reported? In the United States, there are a variety of agencies that have varying responsibilities for regulating the safety of products. These include the National Highway Traffic Safety Association (“NHTSA”) (regulating safety issues on roads and highways), Occupational Safety & Health Administration (“OSHA”) (regulating safety issues in the workplace), Consumer Product Safety Commission (“CPSC”) (regulating the safety of consumer products), Environmental Protection Agency (“EPA”) (regulating the safety of human health and the environment), Food and Drug Administration (“FDA”) (regulating safety issues concerning drugs, biological products, medical devices, the nation’s food supply, cosmetics, and products that emit radiation), etc.

G. Document and word control

Legal background. The documents a company prepares in connection with its products often can have as significant an impact in a products liability action as the product itself, and it is wise to remember that anything a company says can be used against it. For example:

- (1) Advertising, promotional and even oral claims about a product can create express warranties where none were intended, can inadvertently create obligations to warn or negate existing warnings, or can depict product performance or use that is dangerous.
- (2) All too often, the defense of a product liability case is made more difficult because an unsophisticated employee many years earlier had prepared, in haste or in anger, a highly inflammatory document that overly dramatized a safety-related problem (e.g., “this product is a ticking time bomb,” “we are always sitting on something of a powder keg as regards our flannelette being so flammable”).
- (3) A manufacturer’s efforts to limit its liability for product-related problems by imposing on its customers disclaimers of warranties and limitations of remedies can be frustrated if these documents do not pass muster under the Uniform Commercial Code or meet other legal requirements. Moreover, it is not uncommon for a manufacturer to find that it has not obtained as much protection under the warranties and indemnities it received from its suppliers as it believed.
- (4) Manufacturers have been unable to prove that their products were designed and manufactured in accordance with applicable regulations, procedures and standards because the documents that would establish those facts either were never prepared or were subsequently destroyed or lost.

Document control checklist. The review of document control procedures should include the following topics:

- (1) *Warranties and indemnities to customers.*
 - (a) With respect to its customers, has the company given warranties, disclaimed warranties, limited the buyer’s remedies, and/or given hold harmless or indemnity agreements?
 - (b) Do these warranties sufficiently protect the company’s interests and are they in compliance with applicable laws? Among the applicable laws that need to be

considered are the Uniform Commercial Code (attempting to uniform the laws of various states concerning sales and commercial transactions), the Magnuson-Moss Act (regulating written customer product warranties) and local consumer protection legislation.

- (2) *Warranties and indemnities from suppliers.*
 - (a) Has the company received product warranties, indemnities, and related documents from its suppliers?
 - (b) Do these documents sufficiently protect the company's interests and are they in compliance with applicable laws?
- (3) *Advertising and promotional material.* Has the company established procedures designed to insure that its advertising and promotional material is consistent with product warnings, instructions and warranties and with the product's performance and proper uses?
- (4) *Patent application.* Are patent applications screened to insure that they do not overstate product performance or product hazards?
- (5) *Educational programs.* Has the company adopted programs and guidelines designed to educate its employees on how to: (i) avoid the preparation of documents that create unintentional risks and problems in defending the company's products; and (ii) prepare documents that will correctly reflect the company's safety-related design and quality control decisions and practices?
- (6) *Document retention.* Has the company adopted a document retention program that is sensitive to the needs of those who must defend in court the safety of the company's products?

H. Uses of the safety review

Once the review process is completed, a decision must be made on the form in which the results of the review should be presented and memorialized. For example, the results can be presented in an oral or written report that the company may wish to treat as a privileged attorney-client communication to be followed up with widely-disseminated directives to various departments of the business. Regardless of the form of the report, it is essential that it be carefully screened to insure that it does not overstate a problem or establish unrealistic standards and goals. Moreover, the company's records should reflect that each recommendation in the report was adopted, deferred, or rejected for reasons that not only *are* responsible but will *appear* to be responsible in the emotionally charged atmosphere of a products liability jury trial.

A company should recognize that evidence of any change in: (1) quality control procedures; (2) a warning; or (3) in the design of a product may be admissible in some courts as evidence that the prior procedure, warning, or design was inadequate or defective or could have been adopted at an earlier time. Those who suggest or carry out any such recommendation should consult with legal counsel so as to minimize that risk.

A company may want to follow up the review with safety seminars or even a product safety manual.

The company's liability insurance carrier should be advised about the review, probably before the review commences. The company should seek significant premium reduction based on the

results of the review, since many liability insurers are willing to consider reductions based on the performance and implementation of a product safety review.

I. **Pre-acquisition reviews**

Far too often a company will acquire another company or its assets only to discover that it has inherited a disastrous product liability problem. The safety review outlined above can be modified and used as a basis for conducting a pre-acquisition review of the acquired company's potential products liability problems. If serious problems are uncovered, the company may wish to terminate the acquisition or seek to determine whether the transaction can be structured so as to avoid or minimize the effects of unusual rules governing successor liability in product cases.

J. **Insurance**

Obtaining the proper insurance against product liability claims in the United States is crucial to any successful strategy to limit a Dutch company's exposure. It may be difficult for a Dutch company to obtain the right kind of insurance. On the one hand, Dutch insurers often exclude products liability claims arising in the United States. On the other hand, the Dutch company may find that buying a separate policy just to cover their products liability exposure in the United States is not cost effective. Still another consideration is that U.S. importers or sellers, in order to insulate themselves from liability, may require that foreign manufacturers obtain product liability coverage from a U.S. insurer and designate the importer or seller as a beneficiary.

It may be necessary for a company to restructure its entire approach to insuring against risk. Insurers offer a host of various products. A Dutch company may want to seek the services of an insurance broker to obtain the right kind of coverage for the best price. Chapter VII lists the contact information of several insurance companies and brokers. Careful planning will require the Dutch company to think about its insurance against U.S. products liability claims in conjunction with its coverage at home and elsewhere outside of the United States.

An alternative approach would be for the Dutch company to arrange to be named as an additional insured on the insurance policy of another company, e.g., the insurance policy of the Dutch company's distributor in the U.S. Also, a Dutch company could enter into an indemnification agreement with, e.g., its U.S. distributor providing for indemnification by the distributor. The advantages and disadvantages of any such alternative arrangement should be carefully evaluated.

Another possible solution that U.S. companies opt for in the face of high insurance premiums is self-insurance or pooling. A company self-insures when it sets aside reserves to meet future claims. Some companies self-insure up to a certain limit and then purchase insurance only for claims that exceed their self-insured limit. Another solution is pooling. Companies may pool reserves to create a self-insurance fund. This may be an alternative for medium-sized Dutch companies.

A related form of insurance whose use has increased in recent years is product recall insurance, either as a stand-alone policy or additional coverage. Standard product liability insurance typically does not cover costs beyond injury to third parties. Product recall insurance covers costs incurred proactively by a company to prevent injury or damage, including communicating the recall to consumers, replacing unsalable products, public relations, crisis management, consultants' fees, and other costs associated with the recall.

IV. **Our Company Has Been Sued. Now What?**

A. **Initial steps**

- *Document retention*

Once a company learns that it has been sued or that a lawsuit against it is about to be commenced, it must take immediate action to preserve anything that could potentially be evidence. If evidence is destroyed after a company knows of a suit, the court can impose serious sanctions on the company even if the destruction was not intentional. These sanctions include monetary penalties, instructions to the jury that they can infer that the destroyed evidence would have supported the plaintiff's case, or even rendering a verdict in favor of the plaintiff.

It is essential that the defendant identify everyone in the company who may have any relevant documents, and all of the collections of relevant documents that may exist, and inform the employees who control those documents to not destroy them.

- *Investigation*

The defendant must retain counsel and begin the investigation of the claims as soon as practicable. Identifying key witnesses and key documents as early as possible is crucial. Product liability suits often turn on a few damaging documents, e.g., an email from an unsophisticated employee that says "We've got a real problem with Product X, it's a ticking time bomb." There may be a perfectly innocent explanation for this email, but it is too late to discover the explanation, if the first time the defendant learns of the email's existence is from the plaintiff's attorney at trial.

- *Insurance issues*

As soon as the company learns about the lawsuit, it needs to begin the process of identifying which insurance policies might cover the claim. Since insurance policies typically require notice of the claim within a stated time period, the company should make sure it follows the notice provisions to the letter. An insurance policy may also require the insured to tender the case to the insurer for the insurer to take over defense costs. In some policies, the insurer may also have the right to control certain aspects of the defense like appointing counsel. Because there may be consequences to having the insurer involved, the company must consider what rights the insurer has and how much control it wants to cede to the insurer. For instance, if the insurer ends up running the litigation, it may be more willing to settle than the manufacturer would be because the insurer tends to view the lawsuit as a liability on its balance sheet that it would rather get rid of for the right price. The manufacturer in contrast may believe other issues are at stake in the lawsuit. The manufacturer could believe the lawsuit will do damage to its reputation if it appears to concede that its product could be dangerous or it could view settlement of one of the lawsuits as potentially triggering a flood of similar suits. These are just two ways the manufacturer and insurer may assign a different value to the suit. It is worth considering these issues carefully before triggering any rights the insurer has under the policy to take more control of the litigation. The manufacturer also has to realize that after its product liability litigation is over, it may have to engage in litigation again with its insurers over how much of its defense costs are covered by its insurance policy. Therefore, the manufacturer should be laying the groundwork while it is litigating its product liability suits to argue that all of its defense expenses were fully justified. Among other things, it can do that by carefully reviewing its legal bills and making sure, where possible, it has received legal opinions that justify its strategic choices.

In addition to insurance, a company needs to review its various contracts and agreements with distributors, agents, corporate predecessors, parts providers, etc. These agreements may provide for indemnification. Furthermore, by agreement a company could be named as an additional insured on another company's insurance policy. This may be covered by agreement and would trigger all of the notice requirements triggered above.

- *Location is everything*

As discussed above, the potential cost of litigation in the U.S. often depends greatly on where the case will be tried. Therefore, a crucial early step in developing a litigation strategy is determining what can be done to move the litigation into more favorable venues. Motions to dismiss for forum non conveniens, motions for removal and motions to change venue are the principal means to deal with this issue.

Aside from relocating the litigation, which is often not possible, thought should be given to which jurisdiction should be the first to hear a case. There are important reasons for having the first case to be tried in the most defendant-friendly court. An early favorable victory may discourage the filing of additional cases. Conversely, plaintiff's attorneys will use an early victory to advertise for more potential plaintiffs. An early victory may also be helpful in generating favorable press. Also, judges in the U.S. like to follow their peer courts. Judges who see that another court has found no evidence that the product was defective will be much more inclined to find the same.

- *The discovery process*

As discussed above, discovery can add tremendous cost to the litigation. It will be crucial to develop a strategy that addresses questions that will make the discovery process manageable: What documents to offer? How to protect trade secrets and confidential documents? How to manage the collection and production of documents?

B. What does the plaintiff have to prove?

- *Design defect*

As explained above the plaintiff must prove that the product was defective. A defect can be a manufacturing defect, a design defect or a failure to warn. There are two basic tests that courts apply to determine whether a defect is present: the consumer expectations test and the risk/benefit test. Under the consumer expectations test, the court asks the jury whether the product posed a risk beyond the level that a reasonable consumer would expect. Under the risk/benefit test, the question is whether the benefit of making the product safer outweighs the cost of making the product safer. This test is often reduced to asking whether a safer alternative design was reasonable.

- *Inadequate warning*

The plaintiff has to show that there was no warning or that the warning was inadequate. In most jurisdictions, once the plaintiff has shown that there was no warning or an inadequate warning, the court will presume that a proper warning would have prevented the injury. Defendants can overcome this presumption, but they must affirmatively do so.

- *Causation*

The plaintiff has to prove both that (1) but for the product's defect, the plaintiff would not have suffered the injury and (2) the product defect is the "proximate cause" of the injury. Proximate cause is a tricky notion, but essentially when there are intervening causes or attenuated causal chains there is no proximate causation. For instance, insurance companies have sued tobacco companies to recover what they have paid out for smoking-related injuries. The tobacco companies have argued successfully that there is no proximate causation because the causal chain between the risk posed by smoking and the increased medical payments is too attenuated.

- *Negligence*

Design and manufacturing defect claims do not require a showing of negligence. In contrast, to prove a failure to warn claim, the plaintiff will have to show that the defendant company knew or should have known about the risk and failed to provide warnings. However, even in manufacturing and design defect cases, a plaintiff may want to show negligence to strengthen his case for punitive damages.

C. How will plaintiff prove these elements of his case?

- *Expert witnesses*

It will usually be necessary for plaintiffs to have experts testify about the proper design or manufacture of the product. It will also be necessary to have an expert testify on causation, typically, a medical doctor. Finally, there will probably have to be an expert on damages. Often the plaintiff will have an economist calculate lost wages and earnings. The defendant will probably want experts on each of these issues as well. This is different from the customary Dutch lawsuit, where experts are appointed by the court.

- *Documents*

Plaintiffs in products liability cases typically try to make the defendants' documents a key to their cases by finding various admissions in company documents. Placing these documents in the proper context is therefore a large part of the defense of products liability cases.

- *Fact witnesses*

The plaintiff will also need fact witnesses to establish his use of the product and his damages.

D. How can a company defend itself?

- *Lack of jurisdiction*

A dismissal for lack of jurisdiction ends the case in that jurisdiction only. A foreign company may not have engaged in enough business in a state to give the state jurisdiction. This depends on two legal rules: the state's long-arm statute and the Constitution of the United States. Each state has a statute (sometimes called long-arm statutes) that defines when its courts have jurisdiction to hear a case. The Constitution imposes a limit on how far states can reach in their jurisdiction. That limit allows states to exercise jurisdiction over a company who placed its product in the stream of commerce, where the product foreseeably ended up in that state and injured someone. However, not all state long-arm statutes go to the Constitutional limit.

- *Forum non conveniens*

As discussed above, forum non conveniens results in a dismissal. However, to receive a dismissal for forum non conveniens the defendant must agree that they can be sued in some other jurisdiction. Therefore, this defense may not end the litigation.

- *Statute of limitations*

The statute of limitations governs how long a plaintiff has to file a suit after the injury. It is usually two years, but there are a variety of extensions available to plaintiffs. In many jurisdictions, the statute of limitations clock will not start ticking until the plaintiff learns of his injury. In some jurisdictions, the clock will not start until the plaintiff learns that the product was the cause. In all jurisdictions, the clock does not start for minors until they reach the age of majority. Nevertheless, the statute of limitations

defense, when available to defendants, is extremely important because it ends the suit without requiring a complex defense.

- *Failure of proof*
 - *Causation*

- *General Causation*

General causation refers to the question of whether the product can cause the type of injury alleged. For example, when the claim is that a particular product caused his cancer, the plaintiff must prove first that that kind of product can cause cancer. Such proof may involve complex issues of epidemiology, toxicology and a variety of complex scientific fields.

- *Specific Causation*

Specific causation refers to the question of whether the product caused the plaintiff's specific injury. Even if general causation is established, the defendant may still prevail by showing that there are other likely causes of plaintiff's injury that cannot be eliminated.

- *Defenses*
 - *Obvious danger defense*

This defense asserts that some risks from products are obvious and do not need to be warned against. For example, the manufacturer of kitchen knives does not need to warn about the risk of being cut.

- *Assumption of the risk*

In limited situations in some jurisdictions, a defendant can show that the plaintiff knew about the potential risk and voluntarily assumed the risk.

- *Misuse defense*

Misuse of a product is a defense in most jurisdictions. When an injury is the result of the misuse of the product, it does not matter whether the product was defective or if there was an adequate warning. However, the misuse defense may not be available where such misuse was foreseeable by the manufacturer and it took no steps to prevent the misuse.

- *Sophisticated user defense*

Sophisticated users do not need to be warned because they are experts in the use of the product. For example, if the product is industrial machinery, the manufacturer of the machines is not required to warn the purchaser about risks associated with its use.

- *Learned intermediary defense*

Like the sophisticated user defense, courts in most states hold that the manufacturer is not required to warn the end user if it warns a learned intermediary who provides the product to the end user. This defense usually applies to medicines and medical devices. If the pharmaceutical company provides adequate warnings to physicians – the learned intermediaries – then it has no duty to warn patients; that is the responsibility of the physician. In some states, the plaintiff must prove that the learned intermediary would have altered his behavior had he received a proper warning. The learned

intermediary defense may not be available where the pharmaceutical manufacturer has engaged in direct-to-consumer advertising and the consumer warning is found inadequate.

- *State of the art defense*

This defense states that a manufacturer cannot be expected to do better than the best technology available at the time. If a manufacturer can show that their product was as safe as the technology at the time could make it, then there was no design defect.

- *Government contractor defense*

A government contractor cannot be liable if they can show the product they supplied to the government conformed to specific government requirements and the manufacturer warned the government about obvious safety problems arising from the government requirements.

E. What about settlement?

- *Roughly 96% of product liability cases settle.*
- *It is crucial to decide on a settlement strategy as soon as possible.*
- *Many cases may not be appropriate for settlement. Often, settlement of products liability cases has the effect of inviting a flood of similar litigation. However, where appropriate, a settlement strategy should be devised early and the opportune timing to bring up settlement should be considered.*
- *When a decision to settle has been made, typically, the value that a defendant should be willing to pay to settle a case is as follows: The defendant should determine how much plaintiff could possibly win and discount that amount by the likelihood that plaintiff will lose. That amount plus the cost to the defendant of litigating the case is an appropriate value for settlement.*

To estimate the value for each part of this formula requires that the defendant begin its investigation of the factual and the legal merit of the plaintiff's claims as soon as possible. Since initially only the defendant has access to many of the facts that will be crucial to the plaintiff's case, it has an advantage in determining the value of the case.

A number of additional factors affect whether and when to settle a products liability case. Because in the U.S. products liability is big money for plaintiff's lawyers, it is important to understand the financial interests of the lawyers on the other side. As discussed above, plaintiff's attorneys work on a contingency fee basis, i.e., a percentage of the final damage award. They absorb most of the financial costs that the plaintiff has to pay to litigate the case, i.e., paying experts, copying costs, paying for transcripts, etc. The attorneys will have agreements to have these costs reimbursed from any verdict or settlement. However, if the plaintiff never wins a verdict or settles a case his attorney will probably be stuck with these costs. Plaintiff's attorneys have an incentive to not waste time or money on bad cases but to concentrate their efforts on cases that can produce a few large damage awards.

To decide on an effective settlement strategy, it is important to understand these incentives. For example, the time and expense required to learn about the design of a product, to copy and review thousands or millions of pages of a company's internal documents, and to find and hire experts to prove that a product causes injury are enormous. While attorneys may not have an incentive to invest this amount of time and money for one plaintiff, if an attorney can recruit enough potential plaintiffs, that investment will become financially feasible because his chances of hitting it big once increase greatly.

Therefore, it is valuable for a defendant to understand whether it is dealing with an attorney bringing one suit alone or an attorney seeking to bring many similar suits involving the same product. Settling with the latter may encourage filing more such suits. This possibility has to be factored into the decision of whether, when, and for how much to settle. This incentive effect, where relevant, will lower the value at which defendants are willing to settle.

Likewise, a defendant company has to take into account other potential costs from continued litigation, such as exposing the company to unfavorable media attention or exposing other areas where a company may have potential legal difficulties. Such downsides to litigating may raise the value of settlement.

- *Timing of Settlement Negotiations*

The timing of settlement has to be tailored to the specific case and may not be entirely within the control of one side or the other since opposing counsel may have a different settlement agenda. The alternatives are:

- (1) *Pre-complaint settlements.* Pre-complaint settlements, except in small cases, are rare. If there is solid ground for believing the case can only get worse as it progresses, a pre-complaint offer or demand may be appropriate. Also, the parties may have greater flexibility at this phase than at any other since neither side will have invested much time in the case, and the plaintiff may not have signed a contingent fee agreement, which means that nearly all of the settlement will go to the plaintiff.
- (2) *Early settlement.* For a company with many products liability cases, the early identification of cases in which early settlements should be pursued can result in substantial costs savings. The candidates for early settlement will vary among industries, companies and product lines. The following types of cases have been identified as suitable for early settlement efforts:
 - (a) small and modest sized cases;
 - (b) cases involving the same product line or similar factual circumstances; and
 - (c) cases in which liability of the manufacturer is clear and damages are modest;Since an early settlement can take place before discovery is completed or even begun, counsel for the parties who agree to attempt such a program must agree to informally exchange information necessary to evaluate the case.
- (3) *Settlement after the close of discovery.* This is an ideal time to settle cases in which the stakes are high enough to justify an extensive discovery program, but not high enough to justify the even greater expense of trial preparation.
- (4) *Settlement during the trial preparation phase.* The earlier in this phase of the case that settlement discussions are begun, the better. As the pace of trial preparation picks up, a settlement offer may not get the attention it deserves and lines of communication may be shut down while legal fees escalate. It may be productive to involve the trial judge in the process at this stage.
- (5) *Settlement on the courthouse steps.* All too many cases end up being settled at this time, with the result that much of the money that could have gone to the plaintiffs is spent on trial preparation costs, and the case is settled in a crisis atmosphere that often results in a settlement that does not reflect the true value of the case.

- (6) *Settlement during trial or an appeal.* Settlement at this stage should reflect new considerations such as the quality of the jury, whether the witnesses' testimony properly withstood cross-examination, etc.

- *Evaluating a Case for Settlement*

In evaluating the case counsel should consider the issues pertaining to liability, causation, damages and defenses that are relevant to the trial plan. In addition, counsel should consider the following factors:

- (1) *The manufacturer's conduct.* A case in which the manufacturer can be portrayed as callously indifferent to the safety aspects of its product is more valuable than a case based solely on strict liability in which there is no evidence of fault on the part of the manufacturer.
- (2) *The manufacturer's product.* Jurors may be more tolerant of products such as life-saving drugs or vaccines than those that generate instant suspicion such as a used car.
- (3) *The manufacturer's ties to the community.* Local, well-respected corporations in the community in which the case is tried often will fare better than foreign corporations.
- (4) *The manufacturer's corporate image.* The national image of a corporation in terms of its sense of responsibility and trustworthiness can influence the jury.
- (5) *The plaintiff's demographics.* The plaintiff's age, life expectancy, occupation, wealth, family status, education, military service record and criminal record will affect the value of the case.
- (6) *The plaintiff's personality.* While the plaintiff's credibility will be openly stressed at trial, his attractiveness and ability to project a warm, friendly, likable impression can be an important factor.
- (7) *The plaintiff's injury.* While the extent, permanency and painfulness of the plaintiff's injury plays a crucial role in terminating the size of the award, less obvious factors such as the plaintiff's response to his injury (self-pitying helplessness versus courageous adaptation) also are important. Published reports of verdicts and settlements of cases involving similar injuries can be helpful in developing the range of reasonably recoverable damages.
- (8) *The attractiveness of the witnesses.* The same factors that are relevant to the plaintiff apply to the witnesses, particularly if they are close relatives or friends of the plaintiff. A corporation also will be judged by the quality of the people who testify on its behalf.
- (9) *The court.* Among the relevant considerations are: the location of the court, its procedures (its jury selection procedures in particular), the type of juror it traditionally uses, the judge's predisposition in products liability cases and his manner of running his courtroom, the speed of the court calendar, the opportunity for interlocutory appeals, the discoverability of documents including the experts' reports, the practice of the court in imposing *additur* or *remittitur*, and the relative size of verdicts.
- (10) *The jury.* Attorneys for defendants have used pre-trial jury research techniques to help them decide whether a case should be settled and on what terms. These techniques include interviews with individuals who are demographically matched with those who would be empanelled, and simulated jury deliberations that are observed by counsel with opinion surveys taken.

- (11) *Opposing counsel.* It may be an exaggeration to say that it is more important to have a good lawyer than a good case, but there is no question that the skills of trial attorneys vary dramatically and can appreciably affect the value of a case.
- (12) *Opposing experts.* The expert witnesses have a particularly important role in products liability litigation, and while they probably have less of an impact on the value of the case than the attorneys, their skill and credibility should not be overlooked.
- (13) *The number of defendants.* Multiple-defendant cases, particularly where the defendants are squabbling among themselves, generally are more valuable than single-defendant cases.
- (14) *Repercussions of a defeat.* The outcome of a products liability case often can have an impact on the manufacturer that is disproportionate to the size of the verdict. A loss or victory can impact numerous similar cases. The commercial appeal of a product can be tarnished by a loss and adverse publicity can have serious consequences.
- (15) *Punitive damages.* A respectable case for punitive damages will add to the settlement value of a case while a frivolous claim for these damages can stiffen the spine of many manufacturers.
- (16) *Cost of defense.* The importance of this factor will vary according to how important the manufacturer views a successful defense of the product.

V. Special Issues Related to Dutch Companies.

- *Can a Dutch company avoid liability simply by distributing its products through a U.S. distributor?*

No. In one case, Duphar, a Dutch manufacturer of the prescription drug ritodrine, distributed through a U.S. distributor, challenged jurisdiction under Kentucky law. *Tobin v. Astra Pharm. Prod., Inc.* 993 F.2d 528 (6th Cir. 1993) *cert. denied sub nom. Duphar v. Tobin*, 510 U.S. 914 (1993). Duphar had submitted a new drug application to the Food & Drug Administration for this drug and participated in studies of the drug conducted in the U.S. to get FDA approval. Duphar licensed an American manufacturer to distribute the drug throughout the U.S. The two companies were to coordinate efforts in dealings with the FDA and information-sharing with the FDA.

First, the *Tobin* court found that using an independent distributor was not a basis for insulation from suit. The court noted Duphar's involvement in getting the new drug application and tests in the U.S. Second, it cited Duphar's planned penetration of the U.S. market, which, it said, was purposeful availment of the privilege of acting in or causing consequences in the forum state. Third, in reply to Duphar's argument that it had not specifically directed activities to Kentucky, the court said:

If we were to accept defendant's argument on this point, a foreign manufacturer could insulate itself from liability in each of the fifty states simply by using an independent national distributor to market its products, . . . Duphar cannot deny that by licensing Astra to distribute ritodrine in all fifty states it employed the distribution system that brought ritodrine to Kentucky.

Id. at 544.

However, it should be noted that the fact that a manufacturer's product ends up in one of the fifty states of the United States is not by itself enough to make jurisdiction proper. If the manufacturer has done nothing to purposely target the U.S. market, jurisdiction is not proper.

- *Can a Dutch company avoid liability simply by setting up a U.S. subsidiary?*

No. If the Dutch company is the manufacturer, it will remain liable as such. Even if the Dutch company is not the manufacturer, it may not escape liability. In a famous case involving lawsuits over breast implants, Bristol-Myers Squibb Co. argued that lawsuits against it should be thrown out because it merely was the sole shareholder of Medical Engineering Corporation, a major supplier of breast implants, but never itself manufactured or distributed breast implants. The Court rejected that argument because there was evidence that it did more than just own shares but had substantial control over its subsidiary.

Among the factors to be considered are whether:

- the parent and the subsidiary have common directors or officers;
- the parent and the subsidiary have common business departments;
- the parent and the subsidiary file consolidated financial statements and tax returns;
- the parent finances the subsidiary;
- the parent caused the incorporation of the subsidiary;
- the subsidiary operates with grossly inadequate capital;
- the parent pays the salaries and other expenses of the subsidiary;
- the subsidiary receives no business except that given to it by the parent;
- the parent uses the subsidiary's property as its own;
- the daily operations of the two corporations are not kept separate; and
- the subsidiary does not observe the basic corporate formalities, such as keeping separate books and records and holding shareholder and board meetings.

In re Silicone Gel Breast Implants Products, 887 F. Supp. 1447 (N.D.Ala.,1995).

Therefore, a Dutch company cannot avoid liability simply by setting up a U.S. subsidiary, even if the subsidiary actually manufactured and marketed the product, as long as the Dutch parent continued to control the subsidiary.

- *Could Dutch companies involved in information services and technology face product liability lawsuits?*

Yes. Information technology is a new and unsettled area. Increasingly, products-liability theories are being applied where recovery is sought for harm occasioned by the design, manufacture, marketing, or use of computer hardware or software. To date, most of these cases have involved claims for repetitive stress injuries, such as carpal tunnel syndrome, attributed to prolonged and intensive use of computer keyboards claimed to be defective in design. One court in such a case ruled against a keyboard manufacturer because of substantial evidence supporting a link between the keyboard's design and the cumulative trauma disorders from which the plaintiff users allegedly suffered. Several other courts, however, have rejected the supposed scientific link, and ruled for keyboard manufacturers.

VI. Trends in Product Liability in the U.S.

A. Tort reform

In recent years, a number of states have enacted statutes aimed at reforming features of the tort system or of the products liability system in particular. The areas in which reforms have been attempted include: joint and several liability, punitive damages, noneconomic (compensatory) damages (damages for pain and suffering, loss of companionship, loss of enjoyment, and the like), prejudgment interest, the collateral source rule, which prohibits defendants from introducing evidence that insurance program has already provided reimbursement, and products liability reform.

Joint and several liability reform has taken on a number of forms. It has included statutes that end joint and several liability entirely, statutes that enact proportional liability, and statutes that do not allow recovery against defendants who fall below a certain level of fault (25% for example). A majority of states have enacted some type of joint and several liability reform.

Punitive damages have faced reform on two different fronts. As noted above, the Supreme Court of the United States has ruled that excessive punitive damages awards can be a violation of a defendant's due process rights. The Court strongly implied that any amount over ten times the size of the compensatory damage award is a violation of due process. The other front is in the legislatures of individual states. A majority of states have enacted some form of legislation limiting punitive damages. These laws have taken a variety of forms: some states have imposed caps on punitive damages, some have required proof of intent and "actual malice," some have raised the standard of proof to "clear and convincing," some have eliminated punitive damages for drugs and devices approved by the Food and Drug Administration, and some states have adopted two, three, or all of these measures. However, several state courts have found caps on punitive damages to violate the right of plaintiffs to a jury trial.

About one third of states have enacted reforms of noneconomic damages, via caps that are either firm or can be set aside under certain circumstances.

More than a quarter of states have enacted reforms of how prejudgment interest is to be calculated. This is one area of reform that has moved in the direction of increasing compensation for plaintiffs. The traditional rule was that prejudgment interest (that is, interest on the value of the damages from the time they were allegedly inflicted to the time a judgment is entered) was not available. These reform statutes now allow that recovery, and sometimes allow an unrealistically high interest rate to be used.

The collateral source rule has been abolished in some states. In others, evidence of collateral sources is permitted with broad exclusions. In still other states, reforms have allowed evidence of collateral sources and allowed offsets where benefits were over a certain threshold. A variety of other modifications of the collateral source rule have also been enacted. Roughly half of the states have enacted some type of reform of this rule.

Several states have enacted products liability statutes to reform specific areas in products liability law. For example, some states permitted liability for failure to warn even though the manufacturer could not have known of the risk at the time it sold the product. This particularly harsh rule was eliminated by statute.

A number of states have adopted statutes of repose, which provide a final point in time after which no claims may be brought.

Some states that have been criticized in the past for such matters as affirming awards of excessive punitive damages, the allowance of mass trials consisting of thousands of litigants spread through the entire country, or tolerance for lawsuits with little scientific support, including Florida, Illinois, Texas, Mississippi and Alabama, have enacted tort reform statutes or have elected more business-

oriented judges to high courts. These developments have limited but not eliminated the special challenges of litigating in these states. Some other states, notably West Virginia, have largely resisted tort reforms. Plaintiffs often work hard to bring litigation in these states and specific districts or counties within these states to try to take advantage of the pro-plaintiff policies.

B. Restrictions on class actions

A series of judicial decisions have made clear that it is not easy to meet the requirements of Federal Rule of Civil Procedure 23 in the context of products liability cases. In particular, *Amchem Prods., Inc.*, 521 U.S. 591 (1997); *Ortiz v. Fibreboard Corp.*, 527 U.S. 815 (1999); *Castano v. American Tobacco Corp.*, 84 F.3d 734 (5th Cir. 1996); and *In re Rhone-Poulenc Rorer Inc.*, 51 F.3d 1293 (7th Cir. 1995), have made certification of classes of injured plaintiffs much more difficult. The result of these cases is to focus attention on the question of whether there is “sufficient unity so that absent members can fairly be bound by decisions of class representatives.” *Amchem*, 521 U.S. at 621.

In a class action, one person or small group of persons designates himself or themselves the representative(s) of the entire class of similarly situated persons. The class may include millions. The representative will litigate their claims without any input from the members of the class. The Supreme Court made it clear that for a class action to be appropriate, there must be a sufficient unity of interests among all of the class members that no conflict of interests can arise among the class members. In products liability cases, however, these conflicts are readily apparent and make class actions inappropriate. Different product users have different injuries with different causes. Some may have no injury at all, but have an interest in making sure that future potential injuries are compensated. Because of these inherent conflicts, the federal courts are becoming increasingly hostile to bodily injury class actions.

As bodily injury class actions, where plaintiffs allege actual physical injuries become rarer, plaintiffs’ counsel have emphasized two additional types of class actions that can be brought in a products liability context: medical monitoring and consumer based class actions. In medical monitoring class actions, which some jurisdictions accept and other have entirely abolished, plaintiffs are not alleging that they have suffered bodily injury. Instead, plaintiffs are seeking compensation to cover the costs of future diagnostic testing to verify that they do not have or do not develop any unrecognized or latent conditions associated with the product in question. Recently, courts in several jurisdictions have rejected medical monitoring class actions for lack of common evidence. In consumer class actions, plaintiffs are seeking a refund for money they spent on a product due to an alleged fraud by the product manufacturer.

While class actions based on bodily injury have been largely eliminated, and while defendants have defeated many consumer class actions in recent years, a recent California Supreme Court decision favorable to consumer class plaintiffs may provide new encouragement for consumer class action claimants who seek return of their purchase price based on the alleged failure to disclose safety risks.

Several states have adopted statutory reforms to restrict class actions. These reforms include adopting the federal definition of class actions and permitting immediate appeal of court orders creating a class. In addition, many states model their procedural rules on the federal courts’ procedural rules. These states tend to look to federal decisions to interpret their own rules. In these states, the federal decisions on class actions have already been adopted or are likely to be adopted in the future, further limiting the use of class actions in the context of products liability.

C. Excluding junk science from the courtroom

With many products liability cases turning on complex issues of causation that require scientific testimony, it is crucial for the manufacturing defendant to exclude “junk science” that falsely implicates its products in causing injuries to product users. While the willingness of courts to exclude dubious expert testimony is welcome in all manner of products liability cases, it is particularly important in toxic tort cases where the quality of expert opinions on the cause-and-effect relationship between

exposure to a chemical or drug and the disease complained of by the plaintiff is becoming a matter of concern to both the legal and scientific community.

In 1993, the United States Supreme Court in *Daubert v. Merrill Dow Pharmaceuticals, Inc.* clarified the grounds upon which an expert's opinion can be excluded or challenged in federal courts. The court provided a number of criteria for determining the reliability of the expert testimony, including whether the theory or technique in question could be and had been tested, whether it was subject to peer review and publication, whether it had a high known or potential error rate, whether it had standards controlling its operation, and whether it had attracted widespread acceptance within a relevant scientific community. The court also made it clear that trial courts must act as "gatekeepers" and exclude unreliable scientific and expert testimony.

More recently, courts have extended *Daubert* to apply not only to scientific expert testimony, but also to technical and experience-based testimony. The factors articulated in *Daubert* are not a checklist or test, and any decision a court makes regarding expert testimony will ultimately be based on the facts of the specific case.

A 2001 study by the RAND Institute for Civil Justice found that *Daubert* has had a positive effect on federal courts. Federal judges are excluding more expert testimony after the *Daubert* decision than they had prior to it. This study also found that this trend was not limited to a small group of judges. However, several state courts have rejected the reasoning of *Daubert* and are far more permissive in allowing expert testimony. Accordingly, as noted above, the court in which the litigation is set is pivotal in determining the outcome and the possible application of *Daubert*.

D. eDiscovery

With advancements in technology, as well as the increasing dependence of businesses on computers and electronic communication, the volume of information stored in digital form has exploded in recent years. While the ability to electronically store and transmit information has been a blessing to businesses, increasing speed and efficiency, it has created an enormous challenge for companies in U.S. litigation to deal with our invasive pre-trial discovery rules.

Digital documents are easy to create, allowing computers to generate records of user activity that can be easily recovered for evidentiary purposes. The prevalence and ease of digital communication has meant that a great deal of information that would otherwise have been lost is now being captured. An e-mail, for example, creates a record of casual communications that would have been lost if conducted by telephone or by the proverbial conversation by the water cooler.

Digital information is extremely easy to duplicate or alter, takes up a microscopic amount of space and can cost next to nothing to store. Therefore, courts are inclined to issue broad orders regarding required production of a wide range of electronically stored materials. Even voicemails, which are now digitally maintained in most businesses, may come under such orders, if not expressly excluded. Although to the court it may seem that all it takes to produce this information is the push of a few buttons, the reality is very different. Because of the volume of the information, its dispersion, and the variety of storage media and software being used, it can be expensive and virtually impossible to recover in a lot of situations. Moreover, it is dangerous to turn over material to an adversary without reviewing it first for privileged information, trade secrets, or information potentially relevant to the case and this necessary preliminary review can be enormously expensive.

While clarifications of the rules surrounding discovery of electronically stored information are relatively sparse, some case law has developed that sheds a little light on how courts will deal with specific issues that can arise. In general, once a party reasonably anticipates litigation, it has a duty to preserve documents, including digital information, which it might reasonably expect to be relevant to the litigation. A party must suspend its routine document retention/destruction policy to ensure the preservation of relevant documents. In most cases, inaccessible backup tapes, used solely for disaster

recovery, may continue to be recycled according to regular company policy, but if this is not made clear at the beginning of the litigation, this practice may be in doubt.

During discovery, a party can serve a document request seeking access to information stored in digital form. Additionally, a party must make automatic initial disclosure of all documents and electronically stored information that it has in its possession, custody, or control, that it may use to support its claims or defenses at trial.

Generally, a party does not have to produce inaccessible forms of digital information unless the requesting party specifically asks for them. The cost of retrieval of such information will be suffered by the disclosing party unless the burden and expense outweigh its likely benefit to the case. This determination takes into account the needs of the case, the amount in controversy, the parties' resources, the importance of the issues at stake in the litigation, and the importance of the proposed discovery in resolving the issue. Whether or not the costs of digital information retrieval will be shifted, wholly or partially, to the requesting party involves an extremely fact intensive analysis and will depend entirely on the specific circumstances of each individual dispute.

Sanctions for failure to properly disclose electronically stored information have become more common and more extensive as e-discovery has become more complicated. In general, parties will not be sanctioned if they have lost the information as a result of good faith routine modifications, overwriting, or deletion. However, even negligent conduct can potentially give rise to serious sanctions, which can become a major problem when a party is overwhelmed by the technical nuances and expenses of preserving and retrieving certain information. It is vital for counsel to develop expertise on the technical details of their client's document storage policies. Counsel must also take affirmative steps to monitor compliance with document hold procedures resulting from impending litigation, including speaking with information technology personnel and re-issuing warnings to employees not to delete or alter anything that might be relevant at trial.

E. Preemption

Historically, when federal statutes governing the production and sale of various consumer products come in direct conflict with specific state laws, the federal law will supersede the state law. This policy has become increasingly important in the world of prescription drugs and other health related products and devices that have federal entities, such as the Food and Drug Administration (FDA), overseeing their production and sale. In *Riegel v. Medtronic*, the United States Supreme Court held that a federal statute governing regulation of medical devices expressly preempts, or displaces, state tort law claims when a device has received FDA premarket approval. While courts have found that in cases involving a medical device, federal law will preempt state law, *Wyeth v. Levine*, a recent United States Supreme Court decision, held that state law is not preempted in a case involving prescription drugs. Contradictions between federal and state law can be very confusing for companies trying to do business in the United States and an understanding of the interplay between the two distinct bodies of law is vital.

Wyeth v. Levine is the most recent decision that sheds some light on how courts will treat the preemption defense in a products liability dispute. In *Levine*, the Court ruled that a pharmaceutical company could not rely conclusively on FDA approval of a drug's warning label to shield it from state law products liability lawsuits based on the adequacy of the label. Although *Levine* only addressed branded drugs, courts have applied its holding to generics as well. This case represents a rather sharp divergence from some previous products liability cases that had ruled that compliance with federally mandated requirements would preempt any additional state guidelines. While the decision in *Levine* will have a profound impact on products liability litigation with respect to prescription drugs, and more specifically the FDA labeling requirements, it remains to be seen what impact, if any, it will have on preemption arguments in other areas. In a series of recent decisions, sometimes relying on *Levine* and sometimes on earlier Supreme Court precedents, several courts have consistently declined to find federal preemption of state law product liability claims involving medical devices, drugs, and automobiles.

Preemption as applied to one area in particular bears mention. The law of some states allows plaintiffs to benefit from proving that a drug manufacturer engaged in fraud in the FDA application process. There is disagreement among the federal circuits on whether or under what circumstances such “fraud on the FDA” claims are preempted. In light of *Levine*, there are indications that the trend may go against this variety of preemption. This issue is especially important to claims brought under the law of Michigan which, alone among the states, grants statutory immunity to manufacturers in claims involving drugs approved by the FDA unless the manufacturer committed fraud on the FDA.

VII. Further Information

The following are some useful sources for further information on products liability in the U.S.:

- Lloyd Dixon & Brian Gill, Changes in the Standards for Admitting Expert Evidence in Federal Civil Cases Since the Daubert Decision (2001), available at <http://www.rand.org/publications/MR/MR1439/MR1439.pdf>.

This treatise, prepared for the RAND Institute for Civil Justice, analyzes the effect of the *Daubert* decision expert testimony in the federal courts.

- "Product Liability and the Pharmaceutical Industry," ch. 7 in U.S. Congress, Office of Technology Assessment, Pharmaceutical R&D: Costs, Risks and Rewards, OTA-H-522 (Feb. 1993), available at <http://www.wws.princeton.edu/cgi-bin/byteserv.prl/~ota/disk1/1993/9336/933609.pdf>.

This chapter discusses the implications of U.S. products liability in the pharmaceutical research and development process.

- Bowman and Brooke LLP, Documenting a Manufacturer's Design Process (1999), available at http://library.lp.findlaw.com/articles/file/00381/004379/title/Subject/topic/Products%20Liability_Risk-utility/filename/productsliability_1_916.

This article examines a recent federal court decision, *Rogers v. Ingersoll-Rand Co.*, 971 F. Supp. 4 (D.D.C. 1997), for guidance on how a company can create and document its design process to withstand scrutiny under products liability law.

- American Tort Reform Foundation, How Does the Civil Justice System Affect Me?, available at http://www.atrafoundation.org/tort_facts.html.

This article examines the effect of U.S. products liability law on the American economy.

- John S. Allee, Theodore V.H. Mayer & Robb W. Patryk, Product Liability (Law Journal Seminars Press).

This is an in-depth treatise on products liability law in the U.S.

Further information regarding insurance coverage for product liability claims arising in the United States can be obtained from the companies listed below.

- Aon Risk Services
Paul van Dalen
Admiraliteitskade 62
3063 ED Rotterdam
The Netherlands
Phone: + 31-10-448-7088
E-mail: Paul_van_Dalen@aon.nl
www.aon.nl
- Marsh B.V.
Eric Snijders
Conradstraat 18
3013 AP Rotterdam
The Netherlands

Phone: + 31-10-406-0453
E-mail: eric.snijders@marsh.com
www.marsh.nl

- Centraal Beheer Achmea
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VIII. **About Hughes Hubbard & Reed LLP and the Authors**

A. **Hughes Hubbard & Reed LLP**

Firm. With offices in New York, Washington, D.C., Los Angeles, Miami, Jersey City, Paris and Tokyo, Hughes Hubbard & Reed LLP offers expertise in a wide-range of practice areas. Hughes Hubbard has more than 330 experienced practitioners working in over 30 specialized practices, from mergers and acquisitions, public offerings, corporate reorganization, real estate and cross-border transactions to securities litigation, arbitration, product liability, antitrust, intellectual property labor, employee benefits and tax, as well as niche practices such as art law and a credit card practice. The firm has a strong track record in representing non-U.S. companies that do business in the United States. Additional information about Hughes Hubbard can be found at www.hugheshubbard.com.

Products liability practice. In the products liability field, Hughes Hubbard's domestic clients include major worldwide pharmaceutical companies, leading manufacturers of railway and power generation equipment, a leading chemical manufacturer, one of the largest manufacturers of dietary supplements and numerous other domestic and non-U.S. manufacturers of consumer products, medical devices and factory machinery. Hughes Hubbard is national counsel on several significant product liability litigation matters and defends clients in courts throughout the country. Its strong international practice includes advising non-U.S. clients concerning product liability matters, including programs intended to reduce product liability risks. Hughes Hubbard & Reed also has extensive and successful experience in arbitration matters related to product defense issues. Through our Paris office, we also represent clients in product liability cases in France and elsewhere in Europe.

Dutch clients. With several attorneys who speak Dutch, Hughes Hubbard is uniquely situated to help Dutch companies that do business in the U.S. These attorneys, as well as other attorneys in the firm, have a broad experience in assisting Dutch companies that do business in the United States. We have extensive knowledge of the pitfalls that Dutch companies encounter when doing business in the U.S. In addition, we have intimate knowledge of Dutch business practices, decision-making procedures and culture. Our attorneys regularly visit the Netherlands to foster strong working relationships with our clients. In working with Dutch clients, we emphasize building long-term relationships in which the client feels comfortable consulting us about any U.S. legal matters. We believe our experience in representing Dutch companies, combined with our firm's long history and superior experience in representing U.S. and international clients in a broad range of areas, makes us the natural place to turn when Dutch companies need U.S. legal advice.

B. **Authors**

Theodore V.H. Mayer. Theodore V.H. Mayer is the Managing Partner of Hughes Hubbard. Mr. Mayer is a graduate of Yale College (B.A. 1974) and received his law degree from Harvard Law School (J.D. 1977). He specializes in complex litigation matters... Mr. Mayer's practice includes coordinating the defense of major pharmaceutical manufacturers in national class action and individual personal injury litigation involving a prescription medicines, and defense of significant product liability actions involving asbestos-containing products, automobiles, and a wide variety of other products. Other work includes successful prosecution of claims on behalf of a Polish automobile manufacturer against a German supplier arising out of a product defect necessitating a large-scale recall. . Mr. Mayer is also the author, with Robb W. Patryk and John S. Allee, of *Product Liability* (Law Journal Seminars-Press). Currently, Mr. Mayer serves as the Chair of the Committee on Product Liability for the Association of the Bar of the City of New York.

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