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Global Legal Group

The International Comparative Legal Guide to:

Product Liability 2007

A practical insight to cross-border Product Liability work

Published by Global Legal Group with contributions from:

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1 Liability Systems

1.1 What systems of product liability are available (i.e. liability in respect of damage to persons or property resulting from the supply of products found to be defective or faulty)? Is liability fault based, or strict, or both? Does contractual liability play any role? Can liability be imposed for breach of statutory obligations e.g. consumer fraud statutes?

Product liability claims may be brought under theories of strict liability, negligence or breach of warranty. A plaintiff bringing a product liability claim must prove that a product was defective due to an unreasonably dangerous condition or characteristic. There are three categories of product defect: (1) design defect; (2) manufacturing defect; and (3) warnings defect, i.e., failure to adequately warn of risks and dangers associated with product use. A product liability plaintiff may recover for injuries to the person, including death, and damage to property.

1.2 Does the state operate any schemes of compensation for particular products?

In limited circumstances, compensation systems have been set up and operated by the federal government. For example, in 1986, Congress created the National Vaccine Injury Compensation Program to compensate individuals or families of individuals who have been injured by childhood vaccines. To obtain compensation, a party must file a claim with the U.S. Court of Federal Claims. A physician then reviews the claim on behalf of the government to determine whether it meets the criteria for compensation. The initial decision regarding the amount of compensation is made by a "special master." A party may appeal the special master's decision to the Court of Federal Claims and then to the Federal Circuit Court of Appeals. A party may sue the manufacturer of a vaccine only if the vaccine is not covered by the National Vaccine Injury Compensation Program or, for vaccines covered by the program, only after the party has sought relief through the National Vaccine Injury Compensation Program and been denied compensation or received an award the party rejects.

1.3 Who bears responsibility for the fault/defect? The manufacturer, the importer, the distributor, the "retail" supplier or all of these?

In most jurisdictions, product liability claims may be asserted against any entity involved in making a product available to the consumer, including manufacturers, wholesalers, distributors and retail suppliers of the product. Some jurisdictions have so-called "innocent seller" statutes or case law that protect retailers from liability arising out of their sale of defective products provided certain conditions are met, such as the availability of jurisdiction over the manufacturer, the availability of adequate remedy against the manufacturer, lack of knowledge of the defect by the seller, and inability by the seller to discover defectiveness of the product.

1.4 In what circumstances is there an obligation to recall products, and in what way may a claim for failure to recall be brought?

A majority of jurisdictions have held that, in the absence of a statutory requirement or action by a governmental regulatory authority, a manufacturer has no duty to recall a product or take steps to remedy defects discovered after the product has already been sold. However, courts in a minority of jurisdictions, including Arkansas, Colorado, Delaware, Hawaii, Illinois, Iowa, Kansas, Louisiana, Minnesota, New Jersey, New York, North Carolina, Texas, Washington, and Wisconsin, have held that a manufacturer does have a post-sale duty to recall or repair a product.

1.5 Do criminal sanctions apply to the supply of defective products?

Criminal prosecution is possible in connection with product liability claims, particularly where there has been an alleged violation of federal or state laws regulating the product at issue.

2 Causation

2.1 Who has the burden of proving fault/defect and damage?

Generally, the plaintiff bears the burden of proving all elements of a product liability claim. Although the elements of a strict liability claim vary according to state law, a plaintiff typically must prove: (1) that the defendant's product caused or contributed to cause the plaintiff's injury; (2) that the product was defective, i.e., unreasonably dangerous, at the time of the plaintiff's injury; (3) the defective condition of the product existed at the time the product left the hands of the defendant; and (4) that the defendant's product was the proximate, or legal, cause of the plaintiff's injury. Under the negligence theory, a plaintiff must prove these elements and that the defendant knew or should have known of the alleged product defect.

2.2 What test is applied for proof of causation? Is it enough for the claimant to show that the defendant wrongly exposed the claimant to an increased risk of a type of injury known to be associated with the product, even if it cannot be proved by the claimant that the injury would not have arisen without such exposure?

A plaintiff must prove both actual and proximate causation. Actual causation entails two components, general and specific causation. To establish general causation, the plaintiff must prove that the defendant's product is capable of causing the type of injuries alleged. To establish specific causation, the plaintiff must prove that the product did cause the particular injuries in the plaintiff. Generally, to establish actual causation, a plaintiff must offer expert testimony that, to a reasonable degree of medical probability, the defective nature of the defendant's product caused or substantially contributed to cause the plaintiff's alleged injuries.

To establish proximate causation, also referred to as legal causation, a plaintiff must establish that the injury is the natural and probable consequence of the defendant's conduct. The concept of proximate causation acts as a limit on the extent of a defendant's liability. A defendant may not be held liable for every consequence that follows the defendant's action; rather, the defendant's liability is limited to the natural and probable consequences of its action or inaction.

2.3 What is the legal position if it cannot be established which of several possible producers manufactured the defective product? Does any form of market-share liability apply?

In the majority of jurisdictions, a plaintiff bears the burden of proving that the defendant manufactured the product that caused the plaintiff's injury. However, a few jurisdictions have adopted market share liability. It was first adopted by the California Supreme Court in a 1980 case involving the synthetic oestrogen drug diethylstilbestrol, also known as DES, which was manufactured by as many as 300 manufacturers between the 1940s and the 1970s. Market share liability has subsequently been adopted in at least five other jurisdictions in the United States, including Florida, New York, Michigan, Washington and Wisconsin.

Under market share liability, a plaintiff may recover for injuries caused by a product identically manufactured by more than one manufacturer even though it is not possible to determine the identity of the manufacturer of the particular unit that caused the plaintiff's injury. The legal requirements for recovering under the market share theory of liability vary in each of these jurisdictions. For example, in California, a plaintiff must join a "substantial share" of manufacturers and each defendant can be held liable for its share of the market unless it proves it could not have manufactured the product that actually caused the plaintiff's injury. In New York, a plaintiff must also join a "substantial share" of manufacturers and each defendant may be held liable for its share of the national market. However, because the New York court adopted market share liability as a method of apportioning defendants' liability according to their alleged total culpability, a defendant may not exculpate itself even if it can show that it did not manufacture the product that actually caused the injury. In Florida, the plaintiff must show that she has made a genuine attempt to identify the manufacturer responsible for her injury, but has no burden to join a substantial share of manufacturers. Each manufacturer joined as a defendant in Florida is presumed to have an equal market share (as determined by the number of defendants in the case) unless it proves that its actual market share was less.

2.4 Does a failure to warn give rise to liability and, if so, in what circumstances? What information, advice and warnings are taken into account: only information provided directly to the injured party, or also information supplied to an intermediary in the chain of supply between the manufacturer and consumer? Does it make any difference to the answer if the product can only be obtained through the intermediary who owes a separate obligation to assess the suitability of the product for the particular consumer, e.g. a surgeon using a temporary or permanent medical device, a doctor prescribing a medicine or a pharmacist recommending a medicine? Is there any principle of "learned intermediary" under your law pursuant to which the supply of information to the learned intermediary discharges the duty owed by the manufacturer to the ultimate consumer to make available appropriate product information?

Where liability is premised on a defendant's failure to warn of risks or dangers associated with use of a prescription drug, the learned intermediary doctrine provides that the defendant manufacturer discharges its duty by warning the prescribing physician of the dangers associated with use of the product. It is then the learned intermediary's responsibility to warn the user. The learned intermediary doctrine applies in cases involving prescription drugs because these products can only be obtained through a licenced physician, who is in a superior position to understand and evaluate the warnings in light of the patient's medical condition and background. The learned intermediary doctrine has also been held to apply in cases involving heavy industrial equipment where an employer acts as the intermediary in instructing employees regarding safe use of the product.

3 Defences and Estoppel

3.1 What defences, if any, are available?

Statutes of Limitation

A plaintiff's claim will be barred if it is not brought within a certain period of time after the plaintiff is injured. Statutes of limitation vary according to jurisdiction and depending on the theory of liability, but can range in duration from one year to six years for personal injury claims. Many states apply a so-called "discovery rule," which provides that the statute of limitation will not begin to run until a plaintiff knows that he has a cause of action. A plaintiff typically has knowledge of a cause of action when he knows, or should know, that he has been injured and that the product at issue may have caused his injury. A minority of jurisdictions liberally interpret the "discovery rule" to prevent the running of the statute of limitation until the plaintiff knows, or should know, that he has been injured, that the product at issue caused the injury and that the defendant engaged in wrongful conduct.

Statutes of Repose

In contrast to statutes of limitation, statutes of repose provide that a claim will be barred if not brought within a specific number of years after the product was manufactured or sold, regardless of when the plaintiff's injury occurs. Time periods for statutes of repose are typically longer than statutes of limitation, but the "discovery rule" generally does not apply to statutes of repose. Thus, statutes of repose are viewed as an absolute time bar on a claim.

The Learned Intermediary Doctrine

See question 2.4 above.

Intervening and Superseding Cause

A defendant in a product liability action may assert as a defence that the plaintiff's injury was caused by the intervening conduct of a party other than the defendant. The intervening conduct may be that of another defendant, of a non-party or of the plaintiff himself (see Comparative Fault/Contributory Negligence below). However, intervening conduct is generally a defence to a product liability claim only if the conduct is also a "superseding cause." Most courts hold that intervening conduct is a superseding cause where the conduct is such that a manufacturer could not be expected to guard against such conduct in the design of the product. Examples of intervening, superseding causes include failure to properly maintain a product, negligent use of the product, use of a product for a purpose not intended or reasonably foreseen by the manufacturer, failure to inspect a product, failure to follow instructions regarding the installation of a safety device, failure to comply with a product recall, alteration of a product, or criminal action.

Comparative Fault/Contributory Negligence

Formerly, many jurisdictions completely barred recovery by a plaintiff where the plaintiff's own negligence caused, or contributed to cause, the plaintiff's injury. Most jurisdictions no longer bar recovery by a plaintiff who is contributorily negligent; rather, they apply comparative fault under which the plaintiff's recovery is reduced if the plaintiff's own conduct contributed to the injury. Some jurisdictions impose "pure" comparative fault to reduce a plaintiff's recovery by the percentage of fault attributed to the plaintiff's negligence. Other jurisdictions apply "modified" comparative fault, which reduces a plaintiff's recovery by the percentage of fault assigned to the plaintiff, but bars recovery if the percentage of fault assigned to the plaintiff reaches a certain level. For example, in some jurisdictions applying "modified" comparative fault, a plaintiff may recover provided her percentage of fault is less than the percentage of fault attributed to the defendant(s). Under this system, a plaintiff may not recover if her fault is equal to that of the defendant(s). In other jurisdictions applying "modified" comparative fault, a plaintiff may recover provided that the percentage of fault attributed to her does not exceed the percentage of fault attributed to the defendant(s). Thus, a plaintiff may still recover where the plaintiff's fault is equal to that of the defendant(s).

Assumption of the Risk

In many jurisdictions, it is a defence to a product liability claim if the plaintiff knew of a product defect, recognised the danger posed by the product, but nevertheless proceeded to use the product and was injured. This defence is different from contributory negligence in that it applies a subjective standard, i.e., what the plaintiff actually knew, rather than the objective standard applied to a contributory negligence determination, i.e., whether the plaintiff acted as a reasonable person under the circumstances.

Pre-emption

Where a governmental or regulatory body has promulgated rules and regulations regarding product safety, some courts hold that product liability claims that, if successful, would require additional conduct by the manufacturer, are pre-empted by the governmental or regulatory rules and regulations.

Compliance With Governmental Standards

See question 3.3 below.

State of the Art

See question 3.2 below.

3.2 Is there a state of the art/development risk defence? Is there a defence if the fault/defect in the product was not discoverable given the state of scientific and technical knowledge at the time of supply? If there is such a defence, is it for the claimant to prove that the fault/defect was discoverable or is it for the manufacturer to prove that it was not?

In negligence actions, the fact that a product was manufactured according to the state of the art, i.e., the level of scientific and technical achievement in the relevant field, is relevant evidence that the manufacturer exercised due care. Evidence that a manufacturer complied with the state of the art may also be relevant in strict liability cases, particularly in a design defect case, where such evidence may be relevant to determine the feasibility of an alternative design, consumer expectations or the standard for design defect. State of the art evidence is, however, inadmissible in some jurisdictions, including Illinois, Montana, North Dakota, and Pennsylvania. Generally, in jurisdictions where evidence of the state of the art is admissible, the burden of proof is on the defendant to prove that it complied with the state of the art. However, in jurisdictions that require a plaintiff asserting a design defect theory to offer proof of a safer, feasible alternative design, the burden of demonstrating the relevant state of the art is on the plaintiff.

3.3 Is it a defence for the manufacturer to show that he complied with regulatory and/or statutory requirements relating to the development, manufacture, licensing, marketing and supply of the product?

In a majority of jurisdictions, a manufacturer's compliance with regulatory and statutory requirements is evidence of due care or lack of defect, but is not conclusive. In a small number of states, including Arkansas, Colorado, Kansas, North Dakota, Tennessee, Utah and Washington, a manufacturer's compliance with regulatory and statutory requirements creates a rebuttable presumption that the product is not defective. In Michigan, a manufacturer of a prescription drug is not liable and the product is not defective or unreasonably dangerous if the drug and its labelling were approved by the United States Food and Drug Administration (FDA).

3.4 Can claimants re-litigate issues of fault, defect or the capability of a product to cause a certain type of damage, provided they arise in separate proceedings brought by a different claimant, or does some form of issue estoppel prevent this?

A plaintiff is not estopped from litigating issues of fault, defect or the capability of a product to cause a certain type of damage where

another plaintiff has unsuccessfully litigated the same issue(s). However, in some circumstances, where an issue is decided against a defendant in one proceeding, the defendant may be precluded from re-litigating the issue in future proceedings involving different plaintiffs.

3.5 Can defendants claim that the fault/defect was due to the actions of a third party and seek a contribution or indemnity towards any damages payable to the claimant, either in the same proceedings or in subsequent proceedings? If it is possible to bring subsequent proceedings is there a time limit on commencing such proceedings?

See question 3.1 above.

3.6 Can defendants allege that the claimant's actions caused or contributed towards the damage?

See question 3.1 above.

4 Procedure

4.1 Is the trial by a judge or a jury?

In both federal and state court, either party may demand a trial by jury. Most federal juries are comprised of six persons and two alternates and verdicts must be unanimous. State court juries are commonly comprised of 12 persons and the number of jurors to render a verdict varies. In some states, unanimity is required, while others require nine of 12 or ten of 12. In state courts using six-person juries, some require five of six jurors to render a verdict.

4.2 Does the court have power to appoint technical specialists to sit with the judge and assess the evidence presented by the parties (i.e. expert assessors)?

A federal court may appoint a "special master" who may serve as a referee, auditor, examiner or assessor to assist the court with complicated issues. Rule 53(b) of the Federal Rules of Civil Procedure provides that reference to a master "shall be the exception and not the rule." Where trial is by jury, a master may be appointed only where the issues are complicated. Where trial is by a judge, the court must show that some "exceptional condition" requires appointment of a master, except in matters of account and difficult computation of damages.

4.3 Is there a specific group or class action procedure for multiple claims? If so, please outline this. Are such claims commonly brought?

A federal court may "certify" or allow a class action to go forward if the requirements of Rule 23 of the Federal Rules of Civil Procedure are met. Rule 23(a) provides that four prerequisites must be satisfied for a suit to be certified as a class action. First, the class of parties must be so numerous that joinder of all members of the class is impracticable. Second, there must be questions of law or fact common to all members of the class. Third, the claims or defences of the parties who wish to bring the claim on behalf of the class must be typical of the claims or defences of the class. Finally, the parties who wish to bring the claim on behalf of the class must be capable of fairly and adequately protecting the interests of the class.

If the four prerequisites are satisfied, Rule 23(b) provides that an action may be allowed to proceed as a class action in the following three circumstances: (1) the prosecution of separate actions by individual members of the class would create a risk of inconsistent or varying adjudications with respect to individual members of the class which would establish incompatible standards of conduct for the defendant, or adjudications with respect to individual members of the class would be, as a practical matter, dispositive of the interests of other members of the class who are not parties to the action or would substantially impede or impair their ability to protect their interests; (2) the defendant has acted or refused to act on grounds generally applicable to the entire class; or (3) questions of fact or law common to the members of the class predominate over questions affecting only individual members and a class action is superior to other methods for the fair and efficient adjudication of the controversy.

Rule 23(b)(3), directs the court to consider the following factors in making a determination whether common questions of fact or law predominate over individual issues and whether a class action would be superior to other methods for adjudication of the controversy: (a) the interests of members of the class in individually controlling the prosecution of separate actions; (b) the extent and nature of any litigation concerning the controversy already commenced by members of the class; (c) the desirability or undesirability of concentrating the litigation of the claims in the particular forum; and (d) the difficulties likely to be encountered in the management of the class action.

If a court determines that the provisions of Rule 23 are satisfied, it may certify the proposed class and allow the representative plaintiffs to litigate the case as a class action. Typically, the representative plaintiffs must provide notice to potential members of the class that they may opt out of the class and pursue their claim individually. If a class member fails to "opt out" of the class, the class member becomes part of the class action and is bound by its result.

4.4 Can claims be brought by a representative body on behalf of a number of claimants e.g. by a consumer association?

Generally, a representative organisation, such as a consumer association, has no standing to file a product liability claim for injuries sustained by its members. However, some such organisations file petitions with governmental regulatory authorities requesting that the regulatory authority take action against manufacturers, such as requiring a recall of the product or imposing additional safety standards.

4.5 How long does it normally take to get to trial?

The length of time it takes to for a case to get to trial varies by jurisdiction. In the federal courts, during the 12-month period ending March 31, 2006, the overall median time to trial was 22.2 months. See Statistical Tables for the Federal Judiciary, March 31, 2006 (www.uscourts.gov/caseload2006/tables/C05mar06.pdf). However, there is great variation within the federal courts during this period, ranging from only 8.5 months in the Western District of Wisconsin and 9.6 months in the Eastern District of Virginia, to

33.5 months in the Eastern District of New York, 34.5 months in the District of the District of Columbia, and 63.0 months in the Western District of New York. See id.

The length of time it takes to get to trial in state court varies by jurisdiction, but comprehensive statistics are unavailable.

4.6 Can the court try preliminary issues, the result of which determine whether the remainder of the trial should proceed? If it can, do such issues relate only to matters of law or can they relate to issues of fact as well, and if there is trial by jury, by whom are preliminary issues decided?

Judges in federal and state courts may use summary judgment procedure to dispose of specific issues or an entire case prior to trial. Rule 56 of the Federal Rules of Civil Procedure and comparable rules in state courts allow a court to enter summary judgment as to specific issues or the entire case where no genuine issue of material fact exists and the judgment may be entered as a matter of law. Courts may use summary judgment proceedings or other pretrial hearings to make determinations regarding the admissibility of expert testimony. Where expert testimony is held inadmissible, these proceedings, referred to as "Daubert hearings" in federal court, may make trial unnecessary if a party is unable to meet their burden of proof without expert testimony.

In contrast to summary judgment, courts may also hold separate trial proceedings regarding preliminary issues, the result of which determine whether it is necessary to try remaining issues. Rule 42 of the Federal Rules of Civil Procedure and comparable rules in state courts allow a court, where convenient or to avoid prejudice, or where conducive to expedition and economy, to order the separate trial of any claim or any separate issue. In such proceedings, the court may go beyond matters of law and make findings of fact. Additionally, the constitutional right of the parties to trial by jury applies in the separate proceedings. Commonly known as "bifurcation," this procedure is frequently sought by defendants facing claims for punitive damages to prevent the jury from considering issues such as the defendant's wealth and other prejudicial evidence irrelevant to the determination of liability and actual damages. In such instances, defendants typically request that the court try issues related to liability and actual damages first and then, only if actual damages are awarded, to consider evidence relevant to punitive damages in a separate proceeding.

4.7 What appeal options are available?

Before appealing a judgment or order to an appellate court, a party may request, by motion, that the court that entered the order or judgment reconsider its order or judgment in limited circumstances, such as where new evidence has been discovered that could not have been previously discovered or where fraud has been committed upon the court.

Appeals may generally be taken only from a "final decision." See 28 U.S.C. §1291. A "final decision" is one that settles the rights of the parties and disposes of all issues in the case. There are, however, exceptions under which an "interlocutory appeal," which is an appeal from a decision that is not final, may be taken. Such instances include orders granting or denying injunctions, orders involving a controlling question of law if an immediate appeal will advance the ultimate termination of the litigation, orders constituting a clear abuse of discretion where the court's legal duty is plainly established, reference of an issue of state law to a state appellate court and other limited circumstances. See 28 U.S.C. §1292. Additionally, an order granting or denying certification of a class action, although not a final decision, may be appealed pursuant to Rule 23(f) of the Federal Rules of Civil Procedure.

4.8 Does the court appoint experts to assist it in considering technical issues and, if not, may the parties present expert evidence? Are there any restrictions on the nature or extent of that evidence?

Parties may present expert testimony in both federal and state courts where such testimony will be helpful to the judge or jury in evaluating the evidence. The admission of expert testimony in federal courts is governed by Rule 702 of the Federal Rules of Evidence. Rule 702 provides that an expert may testify if the expert is qualified by knowledge, skill, experience, training or education and if the expert's proposed testimony is based upon sufficient facts or data, is the product of reliable principles and methods and if the principles and methods have been reliably applied to the facts of the case. Additionally, in evaluating the qualifications of experts and the reliability of expert opinions, federal courts are guided by the U.S. Supreme Court's decision in Daubert v. Merrell Dow Pharms., Inc., 509 U.S. 579 (1993). The Daubert decision sets forth several factors to guide courts in determining whether an expert's opinions are reliable, including whether the expert's method or theory has been tested, whether the method or theory has been subjected to peer review and publication, the rate of error of the technique or theory, the existence of standards and controls applicable to the method or theory, and whether the method or theory has been generally accepted in the scientific community.

State courts have rules similar to Rule 702 and many apply the Daubert decision. However, some state courts still apply the "general acceptance" standard set forth in Frye v. United States, 293 F. 1013 (D.C. Cir. 1923), which was rejected by the Supreme Court in Daubert. Under the Frye test, an expert's opinion is admissible if the technique employed by the expert is "generally accepted" as reliable in the relevant scientific community.

4.9 Are factual or expert witnesses required to present themselves for pre-trial deposition and are witness statements/ expert reports exchanged prior to trial?

In both federal and state courts, parties may take the pre-trial depositions of factual and expert witnesses. Rule 30 of the Federal Rules of Civil Procedure limits the length of a deposition to one day of seven hours, unless otherwise agreed by the parties. State court rules regarding depositions vary by jurisdiction, but typically allow broad latitude for the deposition of both factual and expert witnesses.

Rule 26(a)(2) of the Federal Rules of Civil Procedure requires all parties to disclose the identity of all experts that may be used at trial, including a written report containing a complete statement of all opinions to be expressed and the reasons and bases in support of the opinions, the data or other information considered by the expert in forming the opinions, exhibits to be used in support of the opinions, the qualifications of the expert, including a list of all publications authored by the expert within the preceding ten years, the compensation to be paid to the expert, and a list of all other cases in which the expert has given testimony at deposition or at trial in the previous four years. State court rules regarding the disclosure of expert reports vary by jurisdiction.

4.10 What obligations to disclose documentary evidence arise either before proceedings are commenced or as part of the pre-trial procedures?

The Federal Rules of Civil Procedure and comparable rules in state courts are designed to prevent parties from "ambushing" adversaries at trial with unknown evidence. Accordingly, parties are required to disclose information to be used at trial, including documentary evidence, before trial begins. Rule 26(a)(1) requires all parties, at the outset of a case, without awaiting any discovery requests, to provide copies or a description by location and category of all documentary evidence the party may use to support its claims or defences. Moreover, the parties are under a continuing obligation to supplement their disclosure of such information as it becomes known to them throughout the case.

While courts had applied Rule 26(a)(1) to require disclosure of information that is stored electronically, the Federal Rules of Civil Procedure have recently been amended to specifically include electronic information within the information that must be disclosed at the outset of a case. The changes to the rules were heavily influenced by the Sedona Conference, which is a research and educational institute dedicated to the advancement of law and policy related to complex litigation. Members of the Sedona Conference include leading jurists, lawyers, experts and academics, who convene regularly in conferences to discuss best practices, guidelines and principles related to complex litigation issues, including discovery of electronic information. The revised rules were also heavily influenced by the body of case law that had developed in recent years regarding discovery issues related to electronic information. Most notably, Judge Shira A. Scheindlin, a federal district judge in the United States District Court for the Southern District of New York, issued a series of opinions in Zubulake v. USB Warburg LLC regarding discovery of electronic information. The revised rules, which became effective on December 1, 2006, are discussed in 8.1, below.

Rules 26 through 37 of the Federal Rules of Civil Procedure provide numerous discovery tools which a party may use to obtain relevant information from an adverse party. Parties may discover information relevant to the case by taking depositions of factual and expert witnesses, propounding written interrogatories, requests for production of documents and things, requests for admissions, and physical and mental examinations of a party.

Finally, federal courts and most state courts require the parties, in advance of trial, to exchange written witness and exhibit lists, as well as copies of all exhibits that may be used at trial.

5 Time Limits

5.1 Are there any time limits on bringing or issuing proceedings?

A plaintiff must file suit within the applicable statute of limitations. Statutes of limitation applicable to product liability actions vary by jurisdiction and may range from one year to six years.

A suit is commenced when the plaintiff files the complaint, also called a petition in certain jurisdictions, which contains the relevant allegations and a request for relief. When the complaint is filed, a summons is issued commanding the defendant to appear before the court to answer the complaint. Rule 4(m) of the Federal Rules of Civil Procedure provides that a complaint will be dismissed if plaintiff does not serve the complaint and the summons on the defendant within 120 days of issuance of the summons. A defendant must answer the complaint within 20 days of service of the summons and complaint. State courts have similar rules and similar timeframes, although the time to answer is 30 days in many jurisdictions.

Alternatively, a plaintiff in federal court may request that a defendant waive the requirement of formal service of the summons in order to avoid the costs associated with such service. If a defendant refuses to waive formal service and plaintiff subsequently serves the defendant with the complaint and summons, the defendant must pay the expenses associated with formal service of the summons. Where a defendant agrees to waive service of the summons, the defendant has 60 days after signing the waiver of service to answer the complaint, rather than the usual 20 day period in which to answer where formal service is made.

After the plaintiff files the complaint and the defendant files its answer, federal courts and most state courts issue scheduling orders that govern the discovery, pre-trial and trial phases of the case.

5.2 If so, please explain what these are. Do they vary depending on whether the liability is fault based or strict? Does the age or condition of the claimant affect the calculation of any time limits and does the Court have a discretion to disapply time limits?

Statutes of limitation begin to run when a claim accrues. The time of accrual varies depending on jurisdiction, but generally a claim accrues when a plaintiff has been injured and knows the cause of his injury. Statutes of limitation are "tolled" or suspended, where a plaintiff has not reached the age of majority, is mentally incapacitated or, in some jurisdictions, is imprisoned. The limitations period begins to run again when the plaintiff reaches the age of majority, when the mental incapacitation is lifted or when the period of imprisonment ends.

5.3 To what extent, if at all, do issues of concealment or fraud affect the running of any time limit?

Statutes of limitation are commonly tolled where a defendant commits an ongoing fraud that prevents the plaintiff from realising that he or she has been injured.

6 Damages

6.1 What types of damage are recoverable e.g. damage to the product itself, bodily injury, mental damage, damage to property?

In a product liability claim, a plaintiff may recover for personal injury and wrongful death, including pain and suffering, medical expenses, loss of income, loss of financial support and loss of consortium. A product liability plaintiff may also recover for damage to property, including damage to the product itself and damage to other property. Finally, a product liability plaintiff may recover punitive damages, which are discussed below.

6.2 Can damages be recovered in respect of the cost of medical monitoring (e.g. covering the cost of investigations or tests) in circumstances where the product has not yet malfunctioned and caused injury, but it may do so in future?

Product liability defendants have been ordered to pay for medical monitoring of plaintiffs to detect the future development of latent injuries or diseases. There is, however, a recent trend against medical monitoring in the absence of physical injury.

6.3 Are punitive damages recoverable? If so, are there any restrictions?

Punitive damages are recoverable in product liability actions in most jurisdictions. A plaintiff typically must prove, by clear and convincing evidence, that a defendant acted wilfully, wantonly or with malice in order to recover punitive damages. In numerous jurisdictions, punitive damages are not recoverable unless actual damages are awarded.

The United States Supreme Court has recently struck down a punitive damages award that was 145 times the amount of the compensatory damages award on the ground that such an award was an arbitrary deprivation of property in violation of the defendant's constitutional right to due process. State Farm Mutual Automobile Insurance Co. v. Campbell, 538 U.S. 408 (2003). The Court noted that any award ten times the amount of compensatory damages or larger would likely be unconstitutional on due process grounds. The Court also held that certain factors, such as the defendant's wealth or conduct unrelated to the injury at issue, may not be considered in determining the amount of a punitive damages award.

Numerous jurisdictions have enacted limits on the amount of punitive damage awards, including Colorado, Connecticut, Florida, Kansas, Oklahoma, Texas and Virginia. Additionally, some states require that portions of punitive damage awards be paid to the state, including Georgia and Iowa.

6.4 Is there a maximum limit on the damages recoverable from one manufacturer e.g. for a series of claims arising from one incident or accident?

There is not a limit on the amount of monetary damages recoverable from one manufacturer. However, some states limit the number of punitive damage awards, but not the amount, to one award that may be recovered from a single defendant for any act or omission, regardless of the number of claims that arise.

7 Costs / Funding

7.1 Can the successful party recover: (a) court fees or other incidental expenses; (b) their own legal costs of bringing the proceedings, from the losing party?

Rule 54 of the Federal Rules of Civil Procedure provides that a prevailing party may recover costs other than attorneys' fees as a matter of course unless the court directs otherwise. "Costs" are defined by 28 U.S.C. § 1920 to include fees of the court clerk, fees of court reporters for transcripts necessarily obtained for the case, fees for printing, witness fees (limited under 28 U.S.C. § 1821 to $40 per day plus mileage and reasonable travel expenses), copying costs and fees of court-appointed experts and translators.

Attorneys' fees are generally recoverable only where specifically authorised by a statute creating a cause of action, such as claims of alleged civil rights violations, and are typically not recoverable in product liability suits.

7.2 Is public funding e.g. legal aid, available?

Although a criminal defendant is entitled, under the Fifth Amendment to the United States Constitution, to the effective assistance of legal counsel, which requires federal and state governments to pay the costs of securing such counsel for indigent defendants, no corresponding right to counsel exists in civil cases.

There are, however, a variety of sources of legal aid, both public and private to assist indigent litigants in prosecuting their cases. A major source of such legal aid comes from the various state bar organisations. Additionally, attorneys are generally encouraged and expected to provide a portion of their services pro bono, i.e., free of charge, to indigent clients.

7.3 If so, are there any restrictions on the availability of public funding?

Because of the numerous and diverse nature of sources of legal aid in the United States, it is not possible to provide a comprehensive overview of restrictions applicable to the provision of legal aid. Virtually all sources, however, have specific income thresholds beyond which legal aid will not be provided.

7.4 Is funding allowed through conditional or contingency fees and, if so, on what conditions?

Contingency fees are allowed in the United States. Various conditions and ethical considerations apply in each jurisdiction, but most jurisdictions allow contingency fees of up to 30-40% of the judgment awarded to a party, provided that the parties enter into a fee arrangement in advance.

8 Updates

8.1 Please provide, in no more than 300 words, a summary of any new cases, trends and developments in Product Liability Law in your country.

On December 1, 2006, the Federal Rules of Civil Procedure were revised to specifically address discovery of "electronically stored information." Rule 34 indicates that "electronically stored information" is broadly construed and includes "images and other data or data compilations stored in any medium from which information can be obtained [and] translated, if necessary, by the respondent into reasonably usable form."

Rule 26(a)(1) requires the parties to include in their initial disclosure "a copy of, or a description by category and location of, all documents, electronically stored information, and other tangible

things that are in the possession, custody, or control of the party." This revision requires counsel to understand and be prepared to disclose a party's system of electronic document management early in a case.

Rule 26(f) requires the parties "to discuss any issues relating to preserving discoverable information" at the outset of the case. Rule 26(f) also contains new paragraphs (3) and (4), which require the parties to confer at the outset of the case regarding "any issues relating to disclosure or discovery of electronically-stored information, including the form in which it should be produced," and "any issues relating to claims of privilege or protection as trial-preparation material, including - if the parties agree on a procedure to assert such claims after production - whether to ask the court to include their agreement in an order."

Rule 34(b) allows a party requesting production of electronically stored information to designate the form in which it wants the information produced. Moreover, if the request does not specify the form of production, the responding party must produce the information in the form in which it is ordinarily maintained or in a form that is reasonably usable.

Under Rule 26(b)(2), a responding party need not produce electronically stored information from sources that it identifies as not reasonably accessible because of undue burden or cost. If the requesting party seeks to compel discovery of such information, the responding party has the burden of showing that the information is not "reasonably accessible," and the court may order such discovery if "good cause" exists. Rule 26 also provides that "[t]he court may specify conditions for the discovery," suggesting that the court may shift costs to the requesting party.

The new rules also include a "safe harbour" in Rule 37 which provides that, "absent exceptional circumstances, a court may not impose sanctions…under these rules on a party for failing to provide electronically stored information lost as a result of the routine, good-faith operation of an electronic information system."

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Harvey L. Kaplan is a partner in the law firm of Shook, Hardy & Bacon L.L.P., headquartered in Kansas City, Missouri. Harvey chairs the firm's Pharmaceutical and Medical Device Litigation Division. He graduated from the University of Michigan and from the University of Missouri-Columbia Law School where he was a member of the Missouri Law Review.

Mr. Kaplan is a Fellow of: the International Academy of Trial Lawyers; the International Society of Barristers; and the American Bar Foundation. He has tried many high profile pharma cases, and he is well known for defending pharmaceutical and medical device companies in national products liability litigations. His litigation practice also includes other products liability cases and commercial litigation.

Mr. Kaplan has served on the Board of Directors of the Defense Research Institute (DRI) and the International Association of Defense Counsel (IADC). He was also Director of the IADC Trial Academy.

He has been recognised as one of the most highly regarded lawyers globally in the field of products liability by *The International Who's Who of Product Liability Defence Lawyers* and by *The International Who's Who of Business Lawyers*, where he was described as "…an 'eminent practitioner with international experience and standing' and an expert in the pharmaceutical field." *Chambers USA* said about him: "…he is described by grateful beneficiaries of his expertise as 'one of the premier pharmaceutical lawyers in the country.'" He was selected by *Lawdragon* for its inaugural list of the 500 leading lawyers in America in 2005 and again in 2006. *Lawdragon* also named him one of the 500 leading litigators in America and said: "For the makers of drugs and implants, he's the antidote to products liability claims." Mr. Kaplan was recognised by *Missouri & Kansas Super Lawyers* as one of the top ten lawyers in both states.

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From 1995-96, John was an Ambassadorial Fellow with Rotary International at the Eberhard-Karls Universitaat Tuebingen in Tuebingen, Germany. As an Ambassadorial Fellow, John studied European Government and History. His fluency in German is certified by the Pruefung zum Nachweis deutscher Sprachkenntnisse (PNdS). Additionally, in 1997-98, John studied international law in London through the Notre Dame London Law Programme.

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Shook, Hardy & Bacon L.L.P.

Shook, Hardy & Bacon L.L.P. (SHB) is an international law firm with a legal legacy spanning more than a century. SHB was established in Kansas City in 1889 and today has grown to more than 2,250 employees worldwide, with 500 attorneys and 325 research analysts and paraprofessionals. The firm has ten offices strategically located in: Geneva, Switzerland; Houston, Texas; Kansas City, Missouri; London, England; Miami, Florida; Orange County, California, San Francisco, California; Tampa, Florida; Washington, D.C.

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