GLG

Global Legal Group

The International Comparative Legal Guide to:

Product Liability 2006

A practical insight to cross-border Product Liability work

Published by Global Legal Group with contributions from:

Arnold & Porter (UK) LLP
Basham, Ringe y Correa, S.C.
Bingham McCutchen LLP
Blake, Cassels & Graydon LLP
Clayton Utz
Crown Office Chambers
Cuatrecasas Abogados
Dechert LLP
Dr. K. Chrysostomides & Co.
Ferrere Abogados
Fiebinger, Polak, Leon & Partner Rechtsanwälte GmbH
Freshfields Bruckhaus Deringer
Georgiev, Todorov & Co.
Grischenko & Partners
Hofmeyr Herbstein & Gihwala Inc.
Jadek & Pensa
Jose Lloreda Camacho & Co.
Kim & Chang
Kromann Reumert
Kyriakides Georgopoulos & Daniolos Issaias Law Firm
Law Firm Saladžius & Partners
Lejinš, Torgans & Partneri
Lovells
Lungershausen & Smith
Matheson Ormsby Prentice
NERA Economic Consulting
Raidla & Partners
Reed Smith
Roschier Holmberg, Attorneys Ltd.
Shearn Delamore & Co.
Shook, Hardy & Bacon L.L.P.
Tuca Zbârcea & Asociatii
Winston & Strawn LLP

Chapter 9

Pre-litigation and Crisis Management Planning: The (Company's) Life You Save May Be Your Own

Bingham McCutchen LLP

Peter C. Neger

I. Introduction

Product liability cases are among the fastest-growing areas of litigation in the United States court system. The whole character of these cases has changed in the past decade or so because the plaintiffs' bar is sophisticated, well-financed and utilises highly-developed technology. Moreover, many plaintiffs' lawyers have well-honed media skills which they use to their best advantage to shape public (and, hence, juror) perception long before a case goes to trial. No industry has been spared, and all should be wary of the special challenges presented by product liability cases.

Plainly, there are many excellent strategies which can be pursued to win product liability cases which have been filed and are being actively pursued. This paper, however, focuses on actions which companies and their counsel can take *today* - *before* a lawsuit commences - to reduce, or possibly even eliminate, exposure in the event that product liability litigation arises in the future.

The simple reality is that the defense of many product liability cases is *reactive*. After a complaint is filed, a company spends the majority of its energy responding to the litigation pressures placed on it by the plaintiff. This is frequently the case because the company defendant has not developed and implemented a well-conceived pre-litigation plan. A pre-litigation plan is like a fire evacuation plan - if a plan is developed, practiced and becomes routine, it could have the effect of saving a corporate life.

II. General Principles

Let's start with a couple of general principles. *First:* development and implementation of any pre-litigation or litigation strategy is a collaborative process. Inside general counsel and others in management of a company have to be involved because they know best the policies and procedures currently in place in their company; they know the policies and procedures most likely to be accepted and followed by their company's employees; and - perhaps most importantly - they know the policies and procedures that fit best with their company's business objectives.

Second, although much of what is discussed in this presentation is geared towards anticipated "mass tort" litigation - involving multiple claims in the federal and/or state courts of several states - many of the principles identified below have equal applicability to single plaintiff, single jurisdiction cases. And make no mistake, it is frequently the case that a single plaintiff lawsuit is just as important to a manufacturer defendant as a wave of litigation because loss of a single plaintiff case can have the effect of opening the floodgates to dozens or hundreds of other cases involving the same product.

Third, while many of the tasks discussed below could be deferred until after litigation is commenced, there are extremely good reasons to undertake most of them in advance of litigation, when a company and its counsel can reflect upon and consider options free from the crisis atmosphere that lawsuits engender.

Outside counsel's most important goal is to identify a client's needs and to satisfy them in a prompt and economical fashion. That goal cannot be attained without a clear and mutual understanding of what the client wants to achieve through its pre-litigation strategy. For this reason, top priority must be given to communication between the lawyer and the client -- early, detailed and frequent communication. Also, the lawyer and the client should promptly seek to identify the client's internal resources that can be brought to bear on many of the pre-litigation tasks. Such a discussion helps to avoid duplication and wasted effort, and to find the most direct route to the result the client wants.

Experience has shown that a litigation budget is an extremely effective way to ensure that a lawyer and a client are on the same page. The budget may have to be very rough at the beginning of the process, and the parties can re-evaluate it from time to time as the scope of the work becomes clearer, but a budget allows both the lawyer and the client to establish expectations, and frequently prevents unhappy surprises down the road.

III. Development of a Pre-litigation Plan

An effective pre-litigation plan has about seven essential elements, assuming that it is designed for a highly regulated industry, such as the pharmaceuticals business. The plan described below is geared towards a pharmaceutical manufacturer, but could be easily adapted for any regulated manufacturing business. Indeed, it could also apply to unregulated industries by simply deleting the elements which deal with regulatory authorities and government reporting requirements.

© Published and reproduced with kind permission by Global Legal Group Ltd, London

A. Document Retention, Collection and Review

The first element in the plan is document retention, collection and review. Lawyers (and regulators) love documents. But with reason: they are frequently contemporaneous records of the history of a company, a product or a process. So, before just about anything else, it makes sense for a lawyer and a manufacturing client to identify, locate and perform a preliminary review of company documents relevant to issues they anticipate would be raised in a product liability litigation.

Depending, obviously, on the nature of the business involved, the types of documents to be reviewed first fall into the following categories:

- company organisational charts;
- product licensing applications (for example, in the pharmaceutical world, the Investigational New Drug application and New Drug Application filed with FDA, or at least those parts relating to safety, warnings, adverse events and labeling);
- safety operations records and periodic safety update reports for the products;
- correspondence regarding the products with relevant regulatory agencies;
- records regarding product labelling, package inserts and changes or proposed changes to those documents;
- adverse event reports and 15-day alert reports for the products, including raw data where available (or any similar incident reports for non-drug products);
- product information and marketing materials;
- scientific and medical literature for drug or medical device products, and analogous literature for other products;
- medical information records for drug products, including inquiries and company responses;
- "Dear Healthcare Professional" letters regarding the products;
- sales representative reports and notes regarding the products; and
- drug interaction records for the products.

In the current environment, a lawyer and client must be prepared to discuss ideas regarding the company's document retention policy, with particular attention to electronic documents and e-mail. In modern complex litigation, a standard strategy by the plaintiff's bar is to throw stones at a company's document retention policy, in the hopes that a spoliation claim (with attendant sanctions and negative inferences) will stick. Therefore, it is of great importance to have in place a defensible document management plan, with all of the following elements:

- **Maintenance of a document retention policy.** In two recent cases where the most severe sanctions were entered against the corporate defendant for discovery violations, the courts noted that the disorganised and haphazard approach to document preservation in litigation could be traced back, in part, to the absence of any corporate document retention programme. *See Zubulake v. UBS Warburg LLC*, 2004 WL 1620866 (S.D.N.Y. 2004); *Coleman Holdings v. Morgan Stanley & Co., Inc.*, 2005 WL 679071 (Fla. Cir. Ct. 2005).

- **Maintenance of a crash recovery plan.** Beyond making good business sense to be able to restore key business information in the event of an unforeseeable loss of data, a crash recovery plan will also assist the litigation team in determining the scope of information that has been maintained by a company's IT department. For example, if IT permanently archives one "base" tape per year and recycles all other backup tapes every thirty days pursuant to the company's crash recovery plan, then defence counsel can credibly argue to the court that the scope of electronic discovery should be limited to the available data, and quickly shoot down any inference that other data is being withheld or intentionally destroyed by the company.

- **Document compliance with and enforcement of the document retention policy and crash recovery plan.** Strict adherence to the policy and plan will allow counsel to credibly argue that available evidence is limited to the materials identified in the document retention policy and recovery plan. Furthermore, the risk that years of data are sitting on company backup tapes is lessened if company policies are routinely monitored and enforced.

- **Educate employees regarding the scope of the retention policy and recovery plan, and their obligation to comply with them.** More than one defendant has been undone in discovery by employee testimony that they were unaware of an obligation to retain certain information, and an obligation not to retain other information. Courts have dealt harshly with defendants when employees destroyed relevant information due to the employees' ignorance of court orders and company policies requiring the retention of the information. *See, e.g., In re Old Banc One Shareholders Securities Litigation*, 2005 WL 3372783 (N.D. Ill. Dec. 8, 2005).

- **Establish a protocol through which all employees are notified of the need to retain information when litigation is threatened or filed.** Recent case law makes it clear that a general directive from management to "preserve the necessary information" is woefully inadequate to fulfill the duty to retain documents in litigation. Rather, employees must be given clear, timely and specific direction as to what information must be preserved. *Id. See also DaimlerChrysler Motors v. Bill Davis Racing, Inc.*, 2005 WL 3502172 (E.D. Mich. Dec. 22, 2005).

- **Create a checklist of key issues that must be addressed in the notice to employees, and provide specific guidance on those issues when notifying employees of the information that must be preserved.** Employees need assistance in understanding what is at issue in a case in order to implement a directive not to destroy documents. Examples of key issues that should be on the checklist include: dates (relevant years applicable to the litigation should be identified); departments, employee names/positions, files by name (files involving customer *x*, or salesperson *y*, etc.); types of data (design, production, sales, purchasing, patents, etc.); and key words (emails referencing the words male, female, suicide, etc.).

- **Appoint a team to monitor compliance on a routine and random basis.** Again, courts have dealt harshly with defendants that issued general directives for evidence preservation and failed to follow-up to ensure compliance. A compliance team should be formed to document efforts to inform employees of the retention requirements, and efforts to monitor and ensure compliance.

- **Provide for a means to save the required data in an alternative storage medium to free up company**

© Published and reproduced with kind permission by Global Legal Group Ltd, London

resources for the regular operation of the business. The courts have found it acceptable for a business to transfer relevant electronic data to other storage media and return the regular backup tapes back into circulation. If the cost of freezing the backup system is too high, consider an alternate storage plan for electronic information relevant to the litigation.

■ **Identify costs associated with the retrieval and storage of litigation related information.** A key factor in determining the scope of electronic discovery is whether the cost is justified by the magnitude of the litigation. A well-researched cost assessment of the retrieval of electronic information will be invaluable to the defence in the argument that the court should limit discovery or shift the cost to the plaintiff.

■ **Identify the person(s) within the company who are suitable corporate representatives for depositions regarding the storage, retrieval and document retention plans as they related to electronic information.** Sophisticated plaintiffs' counsel will start cases with the deposition of IT department personnel pursuant to Rule 30(b)(6) notices (corporate representative depositions) to identify where evidence is located, how it is stored and how it can be retrieved. A misstep at this deposition can haunt the defendant throughout the discovery process. A meaningful pre-litigation plan includes identification of those persons capable of explaining the IT system in an accurate manner.

A well-planned, regularly-enforced document retention plan and litigation management plan should provide the company with a sound factual basis to limit the scope of electronic discovery and to avoid sanctions in the face of a claim that the company randomly and selectively destroyed information relevant to the pending litigation.

B. Collection and Review of Scientific and Medical Literature

The *second* element of a pre-litigation plan involves the collection and review of all relevant outside literature.

The law treats a pharmaceuticals manufacturer, for example, as an expert in its field and expects the manufacturer to monitor the medical and scientific literature relating to its products and to respond accordingly. The same is true with other manufacturing companies within their own respective fields. Therefore, a comprehensive product liability audit for a pharma company should include:

- a review of current company procedures for monitoring, collecting, reviewing, indexing and retaining medical and scientific literature for each product;
- a review of the literature itself, with the assistance of in-house and possibly outside experts;
- recommendations for improving monitoring, collection, review and retention policies; and
- recommendations regarding action items resulting from literature review, whether current or prospective.

Proper literature review policies can help insulate a manufacturer from later claims. For example, although the FDA prohibits manufacturers from promoting a product for any unlabeled or off-label use by physicians, the FDA has nevertheless cautioned manufacturers that they should provide adequate labelling for an off-label use if the manufacturer knows or should know that a product is being used for conditions not recommended by the manufacturer. *See* 21 C.F.R. § 201.128; *see also* 21 C.F.R. § 201.57. If the company knows of an off-label use, through articles in the medical and scientific literature, or through complaint letters, its sales force, or inquiries from medical professionals, the company should consider whether to amend its warnings to explain that the off-label use is not approved by the FDA or recommended by the manufacturer, and whether to issue "Dear Doctor" letters to inform the medical community that the safety and efficacy of the off-label use has not been established.

C. Identification and Selection of Consulting Experts

The *third* element of a plan is the identification and selection of *consulting* experts -- not "*testifying*" experts. There is a significant difference between the two, and many attorneys make the mistake of choosing consulting experts based upon the same criteria as those by which they select testifying experts. While it is true that some of the criteria do overlap, there are vital considerations that will lead to different selections.

A good *testimonial* expert will tend to be a specialist within a narrow field, with prestigious credentials and accomplishments within that specialty. A good testimonial expert will also have the comportment and demeanor to appeal to a jury, and the selection of that expert might even be made to accommodate any parochial biases that a jury may possess (regional accents, etc.).

A good *consulting* expert, on the other hand, has a somewhat broader expertise and a concurrent ability to bridge the multiple disciplines of the testifying experts. He or she should also have good business and commercial sense. Ideally, a consulting expert will have extensive experience providing scientific support for litigation and will be familiar with how cases are developed and how he or she can best serve the client's cause. This prior litigation experience is not always a good thing for a testimonial expert, regardless of whether that testimonial expert has offered the same opinion multiple times before (and can therefore be portrayed as a puppet of the defence) or, worse, has previously given a contradictory opinion.

The matter of identifying and recruiting experts is not as straightforward as one might imagine. Many experts are unwilling to involve themselves with litigation or unable to devote the time and attention necessary to serve the client's needs. Others will decline where a substantial project, and fee, cannot be guaranteed. The lawyer and client should use their collective experience and contacts to identify the experts that will best fit the client's litigation needs.

D. Identification and Selection of Corporate Witnesses

In product liability cases, there are standard areas of inquiry that a company can reasonably anticipate. This leads into the *fourth* element of a pre-litigation plan - the identification and selection of corporate witnesses.

A company can serve itself well by having a clear idea of the individuals it would like to designate as witnesses in the event of litigation and by making those individuals aware that both litigation and testimony are very real prospects.

At a minimum, a typical "duty to warn" case involving a

© Published and reproduced with kind permission by Global Legal Group Ltd, London

drug product will involve the depositions of company personnel with the ability to testify knowledgeably about: (i) clinical studies of the product; (ii) the NDA and any supplements thereto; (iii) interaction with the FDA; (iv) product labelling; (v) post-marketing studies and adverse event reports; and (vi) promotion and marketing. Therefore, it is important that personnel such as the chief physician in charge of relations with clinical investigators, the head of medical affairs, the labelling committee and the head of promotion and marketing be made aware of the prospect of litigation and be given guidance with respect to such vital items as written communications and the importance (and pitfalls) of e-mail. For example, the labelling committee should be reminded that it is very important to be able to defend, against the bright light of 20/20 hindsight, every labeling decision that is made, whether that decision was to include or omit a warning about an adverse event.

A lawyer must be fully aware that interviewing company witnesses can have internal "political" repercussions and that some companies therefore prefer to defer such interviews until litigation has already begun. In many instances, however, initial interviews can avoid overtaxing individuals later on, and are the best way to identify the best company communicators. Conversely, these interviews can also identify those individuals who are likely to be problematic witnesses and those currently employing poor judgment in creating and disseminating harmful paper and e-mail trails containing inaccurate, incomplete or otherwise damaging information. Where necessary, early intervention in the form of training should be considered for those employees who are ineffective communicators but whose testimony is essential for the company's defence.

Counsel and the client should also address the issue of which witnesses are most valuable to the company from a retention/attrition perspective. (It becomes much more difficult to control a witness after he or she leaves the company, particularly when the exit is involuntary, and such individuals often turn out to be a plaintiff's most effective witnesses.)

E. Development of Crisis Action Plan

The *fifth* element of a pre-litigation plan is one of the most important - the development of a crisis action plan.

The realities of life often dictate that there is little or no opportunity to pause and reflect about strategy when a significant or sensitive litigation occurs. Oftentimes, the first notice of a lawsuit comes not by service of a summons and complaint, but rather by a telephone call from a journalist seeking a comment about a lawsuit which was filed that very day.

The best practice, therefore, is to have an established crisis action plan under glass, so that when the crisis occurs, the glass can be broken and the plan implemented.

There are innumerable possible elements to a crisis action plan. Here, too, the best plans are the ones that are developed through a collaboration among company representatives, outside counsel and such other professionals as may be appropriate, including, for example, public relations/crisis management experts.

Any meaningful crisis action plan must include the following elements:

- Identification of one or more company spokespersons (whether internal or retained professionals).
- Development of the key messages to be delivered by the company spokespersons and any others who represent the company. This involves creation of certain common themes (for example: XYZ Company puts safety first; the product at issue is designed to save/improve lives or otherwise serves an important unmet medical need; XYZ Company has performed extensive safety and efficacy testing on the product and the product has an exemplary safety profile; etc.). It also involves developing talking points geared towards the specific product in issue (for instance: x has been on the market since 1963 without any prior indication of elevated cardiac risk; there is no medical or scientific literature which indicates an association between x and increased risk of diabetes; etc.).
- Identification of core crisis management team personnel (including representatives of appropriate company major areas - such as medical affairs, regulatory, marketing, quality assurance, investor relations and legal - so that all sectors of the company have an understanding of the company's initial and long-term strategies in response to the crisis and can act in a coordinated fashion). There has to be a relatively small core decision-making group that can advocate on behalf of (and, later, communicate decisions to) the various constituencies in the company.
- Identification of outside legal counsel.
- Development of a plan to retain all relevant evidence (implementation of a system to alert all appropriate personnel to retain all documents and other materials relevant to the crisis so that the company can never be accused of destroying key evidence).
- Sensitising company personnel regarding the significance of documents (especially including internal email correspondence) that is created after the crisis begins. (Hopefully, the significance of written communications will have been made clear to personnel before any crisis occurs, but the significance is of course magnified in the course of litigation or an investigation where the people involved want to share ideas, say "I told you so," cover their backs, etc.) All personnel must be made to understand that every new memo and email they compose will potentially form a part of plaintiff's case.
- Communicating with any product liability or other insurer which may be involved in the crisis to the maximum extent permitted. Management of a crisis goes far more smoothly and there is far less recrimination afterwards if a company's insurer buys into the management/defence strategy and becomes a full partner with the company and its counsel in the successful resolution of the matter.

F. Identification and Analysis of Potential Key Legal Issues

The *sixth* element of the prelitigation plan involves identification of the essential legal issues which are likely to be involved in a product liability case against a company. Following the review of a company's documents, it should be relatively simple for counsel and the client to anticipate

© Published and reproduced with kind permission by Global Legal Group Ltd, London

the key legal issues which will be relevant to the defence of a company's products in litigation. Most are somewhat standard. There may be some which are unique as a result of specific factual issues identified in the document review and interviews of company witnesses. The client and its lawyers could then reach an agreement regarding whether any research would be cost-effective at that time.

G. Identification and Engagement of Trial Counsel in Key Jurisdictions

The *seventh* and final element to be addressed in a pre-litigation plan is the identification and engagement of trial counsel in key jurisdictions. Now, a great deal has been written and said in the past several years regarding the best structure of a defense team in a mass tort litigation. Some companies favour a single national counsel; others believe that regional counsel works best; and still others favour integrated groups of lawyers working together in what has been termed the "virtual law firm".

There has to be a quarterback for the team - a national counsel to work with the client to develop a single, consistent national litigation strategy, to review the company's documents, to identify and to work up the company's corporate witnesses and scientific and medical experts, and to ensure that the company's legal positions taken in Texas are consistent with those taken in Nebraska, Florida and Montana too. (For that matter, an international manufacturing company has to be viewed as acting consistently in every country in which it does business, or at least have a plausible explanation for not doing so.)

A company preparing for litigation will require the services of local trial lawyers to defend particular cases. As a general rule, "mass tort" litigation isn't confined to one geographic area. More commonly, litigation arises across the United States and frequently concentrates in jurisdictions which have been referred to as the "judicial hellholes" of the United States (*e.g.*, Jefferson County, Mississippi; the southern part of Texas; and Madison County, Illinois). Litigation in these jurisdictions is highly political, and the politics are extremely local in nature. Depending upon the identity of a company's national counsel, you may want local counsel to play the lead role (perhaps, even, the exclusive role) in defending the company in the event that a case goes to trial in one of these jurisdictions.

It is frequently the case that a company's national counsel legitimately considers itself to feature a strong roster of experienced and extremely capable trial lawyers. It goes against those lawyers' instincts to cede the lead role at a trial to someone else. Experience has shown, however, that it is oftentimes in our clients' best interests for us to check our egos at the door and to play more of a supporting role in the trial of a case in a jurisdiction in which a local lawyer would present a friendlier face to a judge or jury.

Therefore, it is important to retain local counsel with highly-honed trial skills to represent the company in these jurisdictions. The number of skilled, experienced and trustworthy trial lawyers in certain areas is limited. Where there are potentially multiple defendants with respect to a given product or class of products, several defendants could be competing for the same local counsel. Therefore, hiring the right person before he or she is hired by someone else is an important consideration. This is not to say that a company should retain fifty or more law firms to serve as local counsel, even before litigation is filed anywhere. Rather, a company should consider identifying a small handful of trial lawyers in certain particularly key jurisdictions where the pool is small, the risks are large and the likelihood of litigation is great.

IV. Conclusion

The challenges of product liability litigation are great. The stakes are frequently enormous, the pressures and disruptions are substantial and the risks associated with inadequate planning and preparation are vast. A company which is willing to engage and invest in preparation will find itself making fewer critical decisions on the fly and in the heat of battle, and will often be able to reduce its exposure by demonstrating to the plaintiffs that it is prepared for engagement and will not capitulate because it can't withstand the pressure.

Acknowledgement

This article was produced with the assistance of Janice Howe and Timothy J. Stephens, partners in the Bingham McCutchen LLP Product Liability Group. Ms. Howe is co-chair of the group and is resident in the firm's Boston office; Mr. Stephens is resident in the firm's New York office.

© Published and reproduced with kind permission by Global Legal Group Ltd, London

Peter C. Neger

Bingham McCutchen LLP
399 Park Avenue
New York, NY 10022-4689
USA

Tel: +1 212 705 7226
Fax: +1 212 752 5378
Email: peter.neger@bingham.com
URL: www.bingham.com

Mr. Neger is Co-Chair of Bingham McCutchen's Product Liability Practice Group. He has more than 20 years of litigation experience in both the federal and state courts. Mr. Neger's experience covers all phases of complex litigation, including litigation avoidance counseling, pre-trial discovery, *Daubert* proceedings and trials and appeals.

Currently, Mr. Neger serves as lead national counsel for a pharmaceutical manufacturer in the fen/phen diet drug litigation, involving more than 7,000 individual and class action lawsuits filed in federal MDL and state courts throughout the country. Mr. Neger was also the court-appointed Defense Liaison Counsel in the Ephedra MDL, and serves as national coordinating counsel for a manufacturer of generic methylphenidate. Among other recent matters, Mr. Neger represented another pharmaceutical manufacturer in individual actions involving an anti-coagulant and an immunosuppressant.

Mr. Neger received his B.A. from Yale University in 1977 and a J.D. from Fordham University School of Law in 1981.

BINGHAM McCUTCHEN

Legal insight. Business instinct.

Bingham McCutchen's Product Liability Practice Group is a versatile and battle-tested team ready to defend its clients against the formidable pressures of product liability litigation. Veterans in the courtroom, skilled in science and astute in strategy, our product liability lawyers form one of the strongest defence teams in the nation. Leaders in the defence of pharmaceuticals and medical devices, we represent nationally recognised manufacturers of industrial and consumer products in individual cases and complex, multi-state class actions in state and federal courts throughout the country.

Our lawyers have been instrumental in developing scientific defences and expert testimony to refute claims of general and specific causation. We are known nationwide for our in-depth experience in *Daubert* hearings and other scientific and technical proceedings. Our group includes nationally recognised trial lawyers and former prosecutors. We have preeminent appellate lawyers, who are at home in any appeals court, from the U.S. Supreme Court on down.

We also provide pre-litigation and crisis management counselling and safety audit assistance that may stop litigation before it starts, or significantly reduce our client's exposure should litigation arise.

© Published and reproduced with kind permission by Global Legal Group Ltd, London