

Respond to New Mass Tort Litigation With a Global Strategy

Backed by strong science and a well-organized team, you can prevent tort claimants from creating a new mass tort litigation

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Although responding to a new mass tort litigation arguably involves as much art as it does science, a number of steps can be taken to increase the likelihood of a successful outcome.

Experienced litigators and trial lawyers often analogize complex litigation, particularly mass tort litigation, to war. With mass torts, as with any conflict, if you are unprepared or lack resources, you risk defeat. And, most assuredly, if you lack vision — a global strategy as well as an understanding of the importance of each individual case — you risk defeat.

The trick is, where possible, to avoid a new mass tort altogether. However, even the best-laid plan can be thwarted by, for example, inaccurate and inflammatory media attention.

The guidelines below are directed at litigation involving drugs or medical devices, but have broad application to other types of mass tort litigation.

Retention of Counsel

A number of ways to structure outside counsel include (i) organizing counsel by region; (ii) arranging for national counsel to oversee a number of local law firms; and (iii) regardless of your choice between national and regional counsel, selecting a national science/expert development/trial team.

Factors that may dictate the best arrangement for a particular company or a particular litigation include the number of cases, their location and their scientific and legal complexity.

A national counsel/local counsel structure permits centralization of efforts under a single roof, at least for purposes of case management. This model only can be effective, however, if the attorneys and paraprofessionals assigned to your litigation at the national counsel firm actually have experience in drug or medical device litigation. A commercial litigator, even an experienced

trial attorney, will not have the necessary facility with science to prepare, manage and try your cases successfully.

By constructing a regional counsel network, a company may have access to a greater number of attorneys with drug or medical device experience. What one gains in breadth, however, one may lose in overall organization. It may prove to be more difficult to produce consistent, coordinated work product in the absence of a single coordinating firm. This can be addressed successfully by in-house counsel acting as the national co-ordinator, assuming, of course, that your litigation manager has sufficient time.

Regardless of whether one chooses national or regional counsel, in the age of *Daubert* and complex challenges to the admissibility of scientific evidence, it is critical to assemble a national science team. You should select members of this team not on the basis of the firm that they are with, but on the basis of that individual attorney's skill and experience in working with scientists and medical professionals in developing the medical causation defense.

In the electronic age, geography also should have little bearing on the selection process, as individual attorneys can work together as a team regardless of where they reside. If, as with the Phentermine defendants in the Fen-Phen litigation, the team mounts an early and successful *Daubert* challenge, your company may be out of the litigation at an early stage. Even if such an excellent result is not possible, your science/expert development team will be prepared to try your cases when the time comes.

Qualities of Counsel

Given the complexity and stresses of mass tort litigation, there are certain qualities to consider in choosing outside counsel. Although too many exist to enumerate here, several qualities are essential:

*Team Players — First, and foremost, hire team players. Your lead attorneys must be both good listeners

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and good communicators. A willingness to collaborate with others will ensure an open exchange of ideas and will increase the likelihood that your company will benefit from the best each attorney has to offer.

*Credibility — Your attorneys must have credibility with courts, with co-defense counsel and with opposing counsel. Attorneys who have prior experience with those judges that have become known as the “mass tort” judges certainly can assist your litigation. Better yet, however, hire attorneys who have developed a significant rapport with these judges — attorneys whom judges consider straightforward and effective.

Similarly, attorneys with strong relationships with co-defense counsel can ensure that your positions are given due consideration in collaborative efforts with other defendants, such as in the preparation of *Daubert* motions and national strategy.

Finally, look for attorneys with reputations of trustworthiness among plaintiffs’ counsel. For example, you want an attorney whom opposing counsel takes at her word when she advises opposing counsel that no further settlement authority is available and, on that basis, settles the case.

*Case Management Skills — In addition to trial skills, outside counsel in a mass tort litigation must possess both the ability to manage thousands of cases and the resources to keep the day-to-day activities under control. This requires having properly trained associates and paraprofessionals, as well as appropriate technology, to organize and store case information.

*Expertise — In the subspecialties of drug and medical device product liability defense work, a traditional large law firm may not be necessary. Focus instead on identifying lawyers and firms with a depth of experience in these fields. Again, even an experienced commercial trial attorney may not have the requisite expertise in science or in the management of mass torts.

*Cost Savings — Companies incur enormous expenses in defending mass tort litigation. Accordingly, outside counsel should make cost-effective choices about case management and analysis. Look for firms that demonstrate comfort with technology such as case management databases and Extranets.

Similarly, outside counsel should have one or more trained legal nurse consultants on staff. If your attorneys send cases outside the firm rather than conducting their own medical analyses, you will find yourself facing high vendor bills and potentially inadequate work product.

Team Organization

The strength of the company’s case will not matter if your defense team is not well-organized. If, for example, responses to discovery are not centralized, and different attorneys around the country serve inconsistent answers to plaintiffs’ discovery, the company will find itself explaining these inconsistencies to a judge or jury.

Accordingly, outside counsel should organize teams promptly to manage each key segment of the company’s response to a new and potentially mass tort litigation.

Although there may be significant overlap in assignments and

responsibilities, consider creating the following teams:

*Science/Expert Development Team — This team will identify and prepare expert witnesses in each key area of science. It also will develop working knowledge of the studies performed as part of the drug’s or medical device’s development, the post-marketing studies, the epidemiological studies and the mechanistic studies. A subcomponent of this team, or a separate team, will develop your *Daubert* challenges to the plaintiffs’ proposed expert testimony.

*Discovery Team — This team will work with in-house counsel to identify, assemble and analyze corporate documents, including the New Drug Application. The team will respond to omnibus discovery in the multidistrict litigation setting and will coordinate individual discovery as needed.

To reduce costs, a company may wish to staff this team in part with in-house attorneys or paraprofessionals, under the supervision of outside counsel.

*Settlement Team — This team will address the multidistrict litigation process, including negotiation of global case management and discovery orders. This team also may assess potential advantages and disadvantages of, and may negotiate, a global settlement.

*Class-Action Team — This team will develop a response to motions to certify class actions, which plaintiffs may file in more than one jurisdiction.

Lines of Communication

Communication lies at the foundation of a successful defense. Establish early on how frequently your teams will meet to discuss strategy, the status of the litigation, the status of individual projects and distribution of tasks. Teams that meet regularly — and conduct business at those meetings efficiently and effectively — will find themselves better able to address the needs of the overall litigation and of the client.

In between, teams and team members can communicate electronically to keep each other apprised of critical rulings and developments in the fact and science investigations, as well as client concerns. The same principles apply whether outside counsel are at the same firm or at different firms around the country.

Moreover, the client, as a key member of the team, must be informed of all significant events. The client remains the ultimate decision-maker and must have the necessary information at her disposal to make sound judgment calls.

Finally, litigation may include a number of other defendants and it is crucial to open lines of communication with their counsel early on in the litigation. Although not always the case, co-defendants may have joint interests in sharing the costs of, and the labor expended in, the defense of the litigation. In particular, communicate with co-defense counsel to coordinate efforts to challenge plaintiffs’ purported medical causation experts. Of course, should co-defendants elect to work together, the feasibility and potential value of joint defense agreements should be considered.

To facilitate communication among members of your teams and the client, consider use of secured e-mail, Intranet

and Extranet Web sites. Use of this technology involves an initial cost commitment but, over time, will reduce costs by reducing maintenance and circulation of paper.

The Documents

Review and analysis of company documents provide the roadmap to understanding a drug's or medical device's development and post-marketing track record. To remain well ahead of your adversaries, begin this task early by identifying all potential sources of documents regarding the drug or medical device and arranging for their assembly in a central location. (For a step-by-step analysis of the document review process, and creation of a document center, see Lifton, "Responding to Discovery Requests in Mass Tort Litigation: Practical and Legal Aspects of Creating a Document Center," *New York Negligence Reporter*, Vol. 5, No. 3 (March 1994)).

Documents to review in litigation involving prescription drugs include the Investigational New Drug and New Drug Application (inclusive of regulatory correspondence between the drug's sponsor and the Food and Drug Administration, as well as animal and clinical studies). You also must review relevant adverse event reports, and, depending on the manufacturer's document-retention policies, internal team correspondence, memoranda, individual and group e-mails, and computer files and databases.

The documents must be reviewed and analyzed to assess the nature and history of the product and the medical condition it was designed to address. Review them to identify the individuals involved in research and development, sales, marketing, regulatory affairs and product safety, and identify "hot documents" that may prove particularly helpful, or harmful, to your case. From there, you will find yourself better equipped to develop the story of the company and its product.

Moreover, you can use technology to simplify this process. A discussion of available technology could easily constitute a separate paper. Briefly, however, consider coding and scanning the documents to permit key word searches. Make the documents available to your team, co-defense counsel and the client through an Extranet Web site.

Finally, if you have followed these steps, you will find yourself in a good position to respond to written discovery effectively. And when you do respond, be consistent. Have one person or one team — either from inside or outside the company — act as a clearinghouse for all discovery responses. Keep both the plaintiffs' case and your affirmative defenses in mind as you respond.

In particular, consider what documents you may need to respond to plaintiffs' case. A document not produced during discovery, for whatever reason, is a document that you cannot use at trial. Last, but not least, obtain an order to protect proprietary information from disclosure beyond the current litigation.

Key Players and Company Witnesses

Through thorough document review, company records and word of mouth, you will identify key individuals who worked

on each phase in the development and marketing of the drug or medical device. As with the document review, focus on key areas of activity, including research and development (pre-and post-marketing studies); regulatory affairs; sales and marketing; and product safety departments.

In the first instance, locating former employees and reaching consulting agreements with them may be even more critical than identifying those people who have remained with the company. Opposing counsel may seek out nonparty former employees for ex parte interviews. If the employee had a negative experience with your company, she may willingly provide opposing counsel with negative information.

In addition, you may require one or more former employees to support your case, such as to show compliance with federal regulations. Accordingly, actively seek out, locate and retain former employees for possible use in building your case. At a minimum, you may have the opportunity to address unfavorable testimony before it falls in the hands of your adversary.

Expert Witnesses

As the ancient Chinese philosopher, Sun Tzu, wrote on the art of war: "Whoever is first in the field and awaits the coming of the enemy will be fresh for the fight; whoever is second in the field and has to hasten to battle will arrive exhausted."

Perhaps in no aspect of the defense of mass tort litigation is this more the case than in identifying and retaining experts. You must be out there first looking for scientists, doctors, engineers or other specialists whose expertise will help you win your case. This means looking to scientists and physicians (i) who were involved with the initial research into the safety and efficacy of the drug or medical device; (ii) who have conducted studies of adverse events or into causation issues; or (iii) who have conducted relevant research or clinical studies.

In seeking out experts in a particular specialty, you can (i) ask for references from current experts, or colleagues in other litigation; (ii) conduct Medline research for authors of pertinent publications; and (iii) research university/hospital departments on the Internet.

For example, the Internet contains an excellent Web site with links to the Web sites of top clinical pharmacology departments around the world. Once you select a particular department's Web site, you will find a wealth of information regarding the current research and areas of specialty for each department.

The defense of typical drug litigation, for example, requires experts in several specialties. These areas generally will include epidemiology, pharmacology, compliance with FDA regulations and the adequacy of warnings. You also will need an expert to explain the indications for the drug or medical device and experts in the disease or condition that the drug allegedly caused. These experts will assist in presenting some of the following points to the jury:

*Epidemiology — What is the importance of epidemiological studies in assessing causation? Is the incidence of the claimed condition/event/injury in the patient

population statistically significant when compared with the incidence in the general population?

*Pharmacology — How does this drug work? What mechanistic studies were conducted? Is the drug capable of causing the condition/event/injury at issue?

*FDA Compliance/Warnings — Did the company comply with federal regulations? Given the state of the science at the time of ingestion, were the warnings accompanying the drug adequate?

*Underlying Condition — Did the treating physician obtain informed consent? What was the standard of care at the time of ingestion, and did the treating physician adhere to this standard?

*Claimed Injury/Condition — Did the drug cause this condition? Are there other possible explanations for the condition, and were the alternate explanations ruled out by the treating physicians in conducting a differential diagnosis?

The silicone breast implant litigation serves as an excellent example of this model at work. In that litigation, experts, including the Rule 706 Science Panel appointed by the multidistrict litigation judge, concluded that the epidemiological studies did not support a causal connection between implants and disease.

Toxicologists testified that silicone is the most biocompatible substance available and is not toxic. Pathologists determined that formation of scar tissue around an implanted medical device was an expected biological event, as was finding some silicone from gel bleed in that scar tissue.

Plastic surgeons discussed informed consent, testified that physicians rely on the universe of what is known about the device in the medical community, not simply on a package insert, for information regarding potential risks and benefits and also testified that the package insert warnings were adequate.

Finally, rheumatologists discredited the notion, advanced by plaintiffs, that silicone gel caused a new condition, atypical connective tissue disease — a condition not recognized by the medical community. They also gave credible testimony that the medical literature did not support plaintiffs' claims that implants cause disease.

Company and Product Profile

All of the other steps you have taken in response to the new mass tort lead to this one: creation of the good company/good product profile. The burden of proof may lie with plaintiffs as a legal matter, but the burden of persuading the jury that your company is a good one, and that your product was tested, and is safe and effective for its intended uses, lies with you.

This requires assembling information, and people to convey it, from all available sources. In the case of a pharmaceutical drug product, the elements of the story to convey to the judge and jury include the following:

- *Company history;
- *Research and development of the drug;
- *Drug's role in treating or curing a challenging medical condition or disease;

*Pharmacology: How does this drug work?;

*New Drug Application and compliance with FDA regulations;

*Pre- and post-marketing studies;

*History of changes in product labeling and warnings;

*Medical Causation: Epidemiology and the mechanistic studies; and

*Context of the condition, disease or injury plaintiffs attribute to your drug.

To create this profile, you will need the relevant documents and the witnesses to introduce them. You may use a company witness to address topics such as corporate history and the drug's development. You likely will turn to your independent experts, however, to teach the jury about basic principles of pharmacology and epidemiology, including what constitutes a valid study and its role in assessing causation.

Managing the Media

The media has come to play a critical role in the creation of mass tort litigation, for example, by jump starting the silicone breast implant litigation with Connie Chung's inflammatory broadcast on "20/20" in the early 1990s. This does not mean that all media coverage will be negative, but you must be prepared.

Assign members of the company's public relations department to track publicity. Organize a team to respond to media attention and equip them with sufficient information to craft a straightforward, positive response. Decide early on whether to take an across-the-board "no comment" position or whether to convey to the media, and thus to the general public, that your company stands behind the product and is aware of no credible evidence of medical causation.

Settlement v. Trial

Decide your strategy at the outset of a new mass tort litigation, and, to the extent possible, stick with it. An immediate retreat into defensiveness, accompanied by an obvious fear of taking a case to trial, will not help you halt a mass tort litigation in its tracks.

For example, early on in the breast implant litigation, Dow Corning, facing significant plaintiffs' verdicts and hundreds of thousands of claims waiting in the wings, chose bankruptcy protection. Other defendants, however, subsequently were able to take advantage of the science. Coupled with a clear message that they stood behind their products and were willing to take cases to verdict, the remaining defendants succeeded in bringing the litigation over systemic injury claims to a close. In the process, they achieved the unthinkable goal of convincing key mass tort judges that plaintiffs' systemic claims were without merit.

Taking an aggressive stance requires a financial commitment. It means preparing each individual case with great care and thoroughness. Starting with the first case, and ending with the last, it means leaving no stone unturned in the discovery process.

As the time approaches to try the first case, both sides will attempt to have their best case or cases go first. You will have battles of “first in/first out” and other case selection methods.

To the extent possible, analyze the pool of cases from which the first case may be selected, and choose a case selection method that will force your opponent to try a weak case first or as many weak ones as possible if the court insists on a consolidated trial.

An aggressive strategy need not be mutually exclusive of settlement efforts. Global settlements, typically part of the landscape of multidistrict litigation, can effectively control the scope and costs of a mass tort litigation. If possible, however, keep the settlement team separate from the trial team so that your trial team does not lose its focus.

Anticipating Mass Torts

In an ideal world, a company could take a number of steps to prevent a mass tort. Short of prevention, at a minimum, be cognizant of possible triggers.

Triggers of a new mass tort litigation involving pharmaceutical drug products may include

- *Label changes;
- *Dear Doctor letters;
- *Voluntary withdrawals;
- *Recalls;
- *Bans on the use of active ingredients;
- *New studies; and
- *Media attention.

In addition, use all available resources, including the Internet, to monitor the monitors. Monitor plaintiffs’ firm Web sites, support group websites and known plaintiffs’ experts.

It is also important to keep an eye on the media and to know what research is in progress at key institutions. Also, watch for new scientific literature and studies, attend conferences directed at plaintiffs’ counsel and be responsive to medical inquiries and claims.

Remain as far ahead of your opposition as you can by anticipating discovery demands and case strategy. Backed by strong science and a well-organized, well-prepared team of committed professionals, your company will be well on the road to preventing tort claimants from creating a new mass tort litigation.