MassTortDefense
LEGAL ISSUES RELATING TO DEFENSE OF MASS TORT CASES & LARGE SCALE PRODUCT LIABILITY CLAIMS
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The "Virtual Law Firm" In Pharmaceutical Mass Tort Litigation

The pharmaceutical industry has been under litigation siege for several years. Plaintiff lawyers regularly seize upon FDA regulatory action, label changes, and new scientific studies concerning potential side effects, as a basis for significant product liability litigation. It matters not that a learned intermediary prescribed the medication. It matters not that the warnings information comported with the state of the art of medical knowledge. The alluring stream of revenue generated by a successful product can be like blood in the water. Plaintiff lawyers have become adept at recruiting clients, utilizing the internet, and product liability actions may descend into mass torts, with tens of thousands of named plaintiffs. From Accutane to Zyprexa, no product seems immune, and few manufacturers seem safe, no matter how robust their pre-launch efforts. That a drug is still approved and on the market does not necessarily prevent significant litigation.

One disturbing feature of today's litigation concerning pharmaceutical products is its potential breadth. Product liability claims require significant defense efforts, and potentially extensive resources. Cases may arise in multiple jurisdictions at once, including the so-called "judicial hellholes" so favorable to plaintiffs. Increasingly, plaintiff lawyers coordinate, such that maximum discovery obtained in one case becomes a mere minimum for what plaintiffs in other cases seek. Defense counsel facing this must bring a variety of skills, including e-discovery experience, medical/scientific expertise, and top trial talent.

In addition to traditional products liability claims based on alleged negligence or strict liability, pharmaceutical mass torts may include securities law claims. When the adverse publicity concerning a new study or FDA action affects stock prices, plaintiffs cry fraud. The litigation may include claims based on state consumer fraud statutes, in which plaintiffs argue they need not show that they actually suffered a side effect, merely that the allegedly undisclosed side effect caused them to pay more for the product than they should have. Those few dollars multiplied in a class action by all the prescriptions written can generate frightening damages. Other plaintiffs, again not even injured, may allege that they are at risk of contracting the side effect in the future, and seek expensive medical monitoring. Yet another group of potential plaintiffs, beyond those patients who actually suffered an alleged injury, are the third-party payers, such as union health funds, who may assert that on behalf of their subscribers they were allegedly economically damaged by the company's conduct regarding a medication. Finally, in addition to direct FDA regulatory review, other government agencies may pile on, including the DOJ/US Attorney. Prosecutors may bring criminal or civil charges, seek significant fines, and put in jeopardy the company's ability to participate in vital government health care programs.

Companies facing product liability cases must be pro-active in this environment. First, they must assess the risks whether the litigation will expand, by factoring in the posture of the FDA, the level of media and interest group interest, and any attention being paid by the DOJ. The status of the key scientific issues must be frankly acknowledged, as well as potential future developments that may affect the state of the art. Lessons may be profitably learned from other mass torts: how vulnerable is the company to the allegations typically made in these cases, such as alleged ghostwriting, improper handling of key opinion leaders in the medical community,

and the degree of off-label usage.

Second, a company that detects a risk of expanding litigation will want to be proactive in setting in place a mechanism to deal with the potential problem. It may be that FDA review leads to no significant label changes; or that prosecutors review basic documents and decline to proceed. A dozen or fifteen cases do not always turn into a mass tort. But if they do, the development can be sudden, and one lesson of history is that early decisions in the litigation can affect – for better or worse – the entire course of the mass tort.

How, then, does a pharmaceutical (or medical device company, for that matter) prepare for a battle that may include many different types of claims, in many different jurisdictions, by many coordinating plaintiff firms? And how does a company secure the quality resources needed to battle what may potentially be hundreds or even thousands of claims?

In recent years, a model that has sometimes been used with success is the so-called “virtual law firm” (“VLF”). In this defense scheme, a company hires lawyer teams from several (typically 4-6) defense firms. Those lawyers are expected to, and indeed are hired on the condition that they will, strive to work with each other seamlessly, as if they were in one law firm rather than several. Hence, the term virtual law firm.

The potential advantages to the client are numerous. First, it allows the client to select what is akin to an all-star team, taking the best trial lawyers from each firm to try the cases, the best legal thinkers from each to draft motions and briefs, the most scientifically adept lawyers at each firm to work up expert witnesses, etc. Second, each firm can concentrate on offering its strengths and true expertise. So, for example, a firm that has great regulatory expertise regarding the product may be invaluable on FDA issues, even outside the regulatory setting, but may not have the capacity or expertise to try cases. The model allows for that firm to handle its niche and also share its expertise with other lawyers in the virtual firm. Third, it allows the client to coordinate among the various kinds of litigation. For example, it may not be efficient to have one firm collecting documents and producing them to the DOJ and a different firm collecting and producing data to personal injury plaintiffs. The need to coordinate among the various types of cases cannot be overstated. Rulings in one case may impact all the other types of cases. Discovery in one may become quickly available in all, despite “protective orders,” because of competing jurisdictions. Depositions taken in one kind of matter may be used in another.

An effective virtual law firm can address many of these issues. A client pursuing this strategy must put together a team that covers each of the major needs, brings talent to each of the essential areas, and can – as a whole – expand and contract to meet the size and scope of the litigation over time. But there is more to a working VLF than selecting the team. The process involves clear communication of needs and expectations. It requires the set-up of appropriate communication tools, from regular meetings and calls, to a secure website database each firm can contribute to and access.

Many clients will appoint one firm as the captain of the team, the steward of the VLF, with responsibility to help in-house counsel make the system work. Attractive candidates for this role will have served as national counsel, co-national counsel, and regional counsel in prior significant litigation. Even if the steward firm will not be handling all phases of the litigation, that they have experience in all phases, or many, is a plus. Clients should seek a firm (all other things being equal) with a reputation for setting the tone for amicable and advantageous relationships in these arrangements.

Managing a VLF can be more daunting than hiring a single firm. The coordination and communication aspects are constant challenges. It may be inevitable that some "sharp elbows" appear. But several companies in the industry have made this model work for them in recent years.

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