A ROUNDTABLE DISCUSSION

THE IMPORTANCE OF CAUSATION ANALYSIS IN MASS TORT CASES

Moderator: *Paul E. Greenberg*
Panelists: *George J. Lykos, Sara J. Gourley, Colleen T. Davies*

A cover story this past spring in Forbes about pharmaceutical mass tort litigation estimated that of the billions of dollars Wyeth has set aside to settle claims concerning usage of its weight-loss drugs Redux and Pondimin, 70 percent went to patients who were not sick. The article also quoted a plaintiffs' attorney who said, "You do not have to prove causation. All you have to prove is that you took the drugs and have the qualifying conditions." In such a climate, plaintiffs' lawyers are likely to become even more aggressive in bringing cases involving patients who have confounding risk factors, provided they can prove these patients took the drug in question for a reasonable period of time.

Despite these apparent trends, rigorous, quantitative causation analysis remains essential in facilitating equitable settlements of mass tort cases. In the absence of such analysis, misallocation of damages awards is almost inevitable, whether it be overcompensation of those whose injuries are not causally connected to use of a given product or inadequate compensation of those whose injuries have been caused by such use.

In the following discussion,[1] four practitioners who have worked in some of the most significant cases of recent years offer perspective on the importance of causation analysis in mass tort cases.

GREENBERG: I think the four of us would agree that the shared goal in the settlement of mass tort cases is to get fair and appropriate restitution to those injured as a result of using a prescription pharmaceutical or device. And part of that means taking into account the numerous factors *other than* defendant's liability that may have contributed to an injury. First, I would like to draw on the perspective of an in-house counsel with extensive experience in mass tort matters. George, what are some of the strategic considerations for a pharmaceutical company faced with mass tort litigation?

LYKOS: My experience in the Baycol litigation has shaped my views on this topic. Baycol was Bayer's anti-cholesterol statin drug, voluntarily withdrawn from the marketplace in August of 2001 after allegations of adverse health consequences including rhabdomyolisis. Up until then, it had been used by six million individuals worldwide. Within 12 months after the withdrawal, Bayer was confronted with 14,000 lawsuits filed on behalf of 50,000 plaintiffs. The first thing any company should do is determine a litigation philosophy that maintains its long-term credibility, and can be translated by inside and outside counsel into a practical defense strategy. We understood that to get through the Baycol crisis, we had to establish and retain credibility with plaintiffs, lawyers, and judges, with financial and market analysts, and with our management and shareholders. We agreed at the outset that if we said we are prepared to settle,


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that we would mean it, and likewise if we said we were going to trial.

GREENBERG: What were some of the principles you decided on?

LYKOS: First, we concluded that settlement and trial were not mutually exclusive, and that strategies forcing us to choose one or the other would never provide enough flexibility to respond to changing circumstances. Equally important, we saw no need to take public positions that could not be maintained for the long haul. Third, we concluded that when consumers were legitimately injured from our product, and the injury was one that we defined as compensable, *and when proof was established about such injury*, we were prepared to settle. This led to the development of what became known as the Bayer settlement program. And finally, we agreed we would not pay—and would not settle—inventory claims. These arise when the plaintiffs' lawyer comes to you, for example, and says, "I have 100 cases, two of which are really compensable because they are real injuries, but if you want to settle those two, you have got to buy my 98 non-injury cases as well." We did not do inventory settlements, plain and simple.

GOURLEY: Inventory claims are a very common tactic. George said 98 other cases. In fact, I have found it is usually a number in the thousands—the cases that the plaintiffs' lawyers themselves call the "pill-taker" cases, where someone simply took the medication and is looking for a settlement, regardless of any demonstration of causation.

GREENBERG: I will add that from an economic perspective, causation analysis is central to arriving at accurate monetary estimates of damages. Yet it does not get quite the attention that it ought to in many of these mass tort cases.

LYKOS: With Baycol, we proceeded based on the belief that plaintiffs had to establish specific causation between the ingestion of the drug and the claimed injury. And by specific causation, I mean, did this product cause this injury to this person. The issue is not, *can* it cause this injury, but *did* it cause this injury.

GREENBERG: How did your focus on causation play out in the courtroom?

LYCOS: We focused on trying to get to trial with the best case first. That we won our first trial in a plaintiff-friendly jurisdiction was a great bonus. To date, we have had five Baycol trials that have gone to final judgment. All resulted in defense verdicts. Cases have been held in what are considered plaintiff-friendly places—Corpus Christi (Texas), Mississippi, and one case in a state court in Philadelphia. We have also prevailed in attempts by plaintiffs to establish medical monitoring classes at the federal and state level, and we continue to defend the company against economic loss cases. In these cases, there were a lot of people who claimed aches and pains, who claimed that maybe this was rhabdomyolysis, but in fact all that was documented was that their muscles hurt, not that they were damaged.

GREENBERG: In my experience, determining the appropriate compensation requires knowing which plaintiffs, if any, were actually damaged as a result of taking the drug, as opposed to other factors.

GOURLEY: Yes, some highly publicized mass torts, like Baycol, have so-called "signature injuries" associated with use of the products. In Baycol it was rhabdomyolysis. In asbestos cases, it was mesothelioma. In these cases, you need to look at specific causation and settle early on those cases where your client's product did in fact cause an injury. In mass torts where the injury has a multitude of potential causes, it is even harder to sort out and settle claims. Cardiovascular events, for example, can be difficult to sort out. These kinds of injuries are alleged in the HRT litigation, in the Vioxx litigation, in the other COX-2 litigations (Celebrex and Bextra), ephedra, and PPA litigation. It is a confounding issue in many mass torts, when the injury is something that commonly occurs even in the absence of the use of the products. While defendants in mass torts with those kinds of injuries will often ultimately win those cases on specific causation, it can take a long time.

GREENBERG: The analytical approach that we often take to damages is based on clinical evidence of elevation of adverse event risk, and it is premised on causation analysis being relevant and appropriate. But attempts to establish causation at the individual level may be resisted, sometimes because of the information requirements or analytical challenges that they present, or because there are overarching concerns for the implications of the findings.

DAVIES: And plaintiffs' attorneys are finding creative ways around causation defenses in areas beyond personal injury. The emerging trend we are seeing now is cases wherein insurance companies and other entities that pay for medications—from healthcare benefit plans and union funds to government entities—are filing lawsuits for *economic* damages. The causal focus in these lawsuits is not between the patient's injury and the product, but is rather between what the defendant did or did not do and the third-party payor's payment. In these cases, the third-party payors are suing the pharmaceutical companies or the medical device manufacturers directly.

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GREENBERG: What harmful conduct by the defendant are they alleging?

DAVIES: Typically, these are claims of product fraud as opposed to product liability. The plaintiffs might allege that a pharmaceutical company failed to warn the Food and Drug Administration (FDA) on adverse events when it received approval to market the product. Or it was promoting off-label uses of the drug. If a pharmaceutical company recalls the product, third-party payors might claim that the drug was not efficacious, and point to the clinical study that triggers product withdrawal. In these cases, the plaintiffs' lawyers are trying to include the *entire universe* of patients in the lawsuit often by alleging that, but for the defendant's actions we, the healthcare entity, would never have put this medication on our formulary. We, the healthcare entity, would never have allowed this medication to be prescribed. And what that uniquely does is it includes *every patient that ever took the drug.* For blockbuster products with over a billion dollars a year in sales revenue, successful class action claims of this type obviously involve huge stakes.

GREENBERG: Coming back to this subject of inventory claims: what are some of the things counsel can do to weed out claims that are not supported by causation analysis?

GOURLEY: One way of forcing the issue is through the use of what are called *Lone Pine* orders, which require that plaintiffs come forward with specific evidence of causation in a case. *Lone Pine* refers to the name of the case that pioneered the way with respect to these issues. These orders are often resisted by plaintiffs' lawyers because they frustrate their desire for inventory settlements. The natural inclination of judges faced with many injury cases is to believe at the outset that all of those cases have some merit, and they need to see that not all of them do before they will issue a *Lone Pine* order.

GREENBERG: How important a role do company scientists play in helping determine what injuries qualify as drug-induced?

GOURLEY: This can be very important. Motions directed to showing that the science does not support the claims can be successful and go a very long way toward reducing the burden of litigation, so you need to involve the company scientists in the process from the very beginning. Lawyers are capable of assessing litigation risk; scientists and physicians need to evaluate the medical issues to guide the lawyers. Armed with the science, lawyers can devise a strategy designed to separate the cases into their appropriate medical category, and attempt to eliminate those that do not qualify as drug-induced injuries.

GREENBERG: Can you give us some examples of how the defense has used science in previous litigations to sort these issues out?

GOURLEY: Sure. One example involves Meridia, an anti-obesity medication. Summary judgment was granted on all cases in the federal court because the plaintiffs' experts were not able to establish a link between the ingestion of Meridia and the cardiovascular events alleged by the plaintiffs in this high-risk population. Portions of claims have been dismissed in other cases. Another possibility is to convene a scientific

panel, as was done by Judge Pointer in the breast implant litigation. The panel evaluated whether breast implants caused the injury alleged by the plaintiffs, and decided that they did not. Unfortunately, in the breast implant litigation, the approach came after years and years of litigation, many settlements, and many payments. Another approach that has not been tried very frequently is to conduct a science tutorial for the judges. Let the plaintiffs' lawyers and the defense lawyers bring scientists to analyze the science behind the claims, and help judges understand early that not all of the cases before them are going to merit compensation. And *Daubert/Frye* motions are powerful tools as well, provided, of course, the science is on your side.

GREENBERG: Let us talk about settlements. I have been involved in a number of cases where the focus has been, for example, on developing payout matrices, where we figure out how many plaintiffs or claimants are likely to come forward and how many of them will have serious adverse events linked to the product. Settlement grids can provide a means to both weed out claims that are not credible and ultimately calculate damages or the potential size of reserves to fund the exposure. Colleen, in your practice, how do you use causation analysis in developing settlement matrices?

DAVIES: A settlement matrix is a difficult thing to put together for a defense counsel. It draws together a lot of the issues that George and Sara have raised. A matrix might address answers to questions such as: Did the claimant have a prescription? Did the claimant take the drug? Was the drug taken for one day or two years? What is the temporal relationship between use of the drug and the injury? Did the claimant have other risk factors associated with the injury? Maybe the claimant had another condition that caused the injury. Or, maybe the claimant was off the drug for six months and was on another medication. You want to be able to plot that level of specificity.

GREENBERG: Would your matrix distinguish between claimants having economic damages versus those with non-economic damages?

DAVIES: Yes, you would want to "grid" all of those. All of these individual causation factors on the medical and factual level get placed into a matrix where the claimants are ranked and given certain points. And then you should note defenses, such as statute of limitations: if Claimant 94 brought his claim two months late, how does that impact his claim? In a lot of the claims we work on, the claimants assert that they *may* suffer an injury or that something *may* occur in the future. And I know in the Gamma Guard litigation, there was a very interesting settlement matrix idea put in place where claimants were to be paid *if* certain contingent events took place. So these are all layers of complexity, and tackling these various causation issues that we fight hard on in the courtroom is equally difficult when we focus on the settlement arena.

Lessons from Practitioners

The insights offered by these four practitioners emphasize the importance of developing strong defense strategies early on in a mass tort case. Such strategies should be aimed at curbing injury claims that cannot credibly be linked to the use of a medication or device. In particular, attention should be focused in four key areas:

1. Setting a corporate philosophy on causation defenses, particularly with regard to settlement strategies. There are two significant tasks that every defendant should initiate when facing mass tort causation issues: 1) defining the company's approach to causation issues early on; and 2) maintaining consistency in the defined approach, whether in a litigation or settlement arena.
2. Using litigation defense strategies to minimize claims exposure. Discovery and pre-trial motion practice are essential tools in causation disputes. Whether through the use of clinical trial evidence, adverse event trends, or motion practice, an aggressive litigation defense remains essential.
3. Eliminating plaintiffs' damage claims lacking a causation basis through quantitative analysis and use of settlement matrices. The challenges associated with causation analysis are not insurmountable. Moreover, such analysis can be extremely valuable in challenging both specific and general causation assertions. A defendant should only be held responsible for damages that are directly connected to injuries caused by use of a medication or device. In approaching settlement discussions, a matrix framework can provide defendants with a means to challenge inflated damage claims. Settlement grids can highlight numerous mitigating risk and damage factors for individual claimants, which helps weed out claims that cannot credibly be linked to the product at issue.
4. Anticipating tactics by the plaintiffs' bar to avoid causation defenses. Cases involving third-party payor claims are becoming more common. Claimants in these cases are not concerned with whether a product is linked to a given injury; instead, they shift the analysis to whether the defendant's marketing of a product is causally related to a third-party payor's reimbursement of the cost of the product. Practitioners should be prepared to face such claims in defending pharmaceutical and medical device clients and remain ever vigilant to prevent the erosion of causation defenses.

GREENBERG: Settlement payments need to fairly reflect both the injury and the strength of the plaintiff's medical claim. And ideally, those payments should not be influenced by the court, the plaintiff's lawyer, or other factors. George, what approach did Bayer take to settlements in the Baycol cases?

LYKOS: One thing we determined at the outset was that our settlement position would be unchanged by venue or other considerations. Settlement values were based on a grid that assigned specific values to specific types of injury. Those values did not change whether we were in a plaintiff-friendly or defense-friendly jurisdiction. Nor did the value change if plaintiffs' counsel demanded a "reputational" premium, that is, "I am entitled to 20 percent more because I am the best lawyer in Los Angeles." That did not matter.

Also, to validate the credibility of our settlement values, we did not require or even ask for confidentiality provisions in the settlement. We wanted everyone to know what we were willing to pay. For those cases in which we felt there was no liability, or the settlement demand bore no reasonable relationship to the injury, we defended the claim to trial.

GOURLEY: George's approach is consistent with my philosophy on this. I cannot overemphasize the importance of establishing the means by which causation is established early on. It is hugely important to decide, in the context of the particular injury you are talking about, what is going to be a sufficient level of proof.

[1] This article is based on a panel discussion and adapted for publication. The panel was held at FDLI's 49th Annual Conference in Washington, DC, in April 2006.