Legal Times
WEEK OF DECEMBER 19, 2005 • VOL. XXVIII, NO. 51
ALM

We've Conducted Our Own Tests

Company-sponsored testing can provide the foundation for a solid courtroom defense, but it's not for the faint of heart. Here are some questions in-house counsel should ask before the studies begin.

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The first trial has gone badly, and your company's product is threatened with even more health-effects litigation. Your scientists have tested the product and are sure it is safe, but there are no definitive studies to counter the plaintiffs' experts' speculative opinions. Someone throws this idea on the table: "Let's conduct our own studies to disprove the plaintiffs' contentions."

Have you just opened a Pandora's box for in-house litigation counsel? Is it a good idea to conduct company-sponsored studies designed and intended to assist the company in winning lawsuits? You'll hear all sorts of recommendations and warnings about such an effort from your consultants and outside counsel, but, ultimately, the responsibility for this decision will fall in the lap of in-house counsel. After all, in-house counsel will have to authorize these studies.

The consequences of a test gone bad can be—not to mince words—severe. This is not an area for the faint of heart. Company-sponsored litigation testing is fraught with pitfalls, and not just minor ones. Mistakes may not only lose a case, they may also destroy the product itself and possibly injure the company's reputation. Of course, the testing has to have sufficient independence to preserve credibility. But at the same time, what if the testing doesn't "work out" in the way everyone expects? Even well-conducted studies that show the product is safe may prove to be of limited help when the plaintiffs point out that the funding for the studies was provided by the company.

IN-HOUSE COUNSEL

Why Take the Chance?

So if there are risks to conducting studies, why do them? The answer lies in the nature of health tort litigation after the Supreme Court's ruling in *Daubert v. Merrell Dow Pharmaceuticals Inc*. Due in part to the plaintiffs bar's successes in asbestos and other tort litigation, novel claims of health effects have exploded in the past two decades. *Daubert*'s enhanced requirements for expert testimony—emphasizing the need for a scientific methodology tested, in part, through peer review and publication—in turn have placed a premium on scientific studies to promote or defend those cases. Plaintiffs thus are increasingly funding, and sometimes publishing, their own studies to support claims and avoid a *Daubert*-based dismissal.

Defendants themselves, however, may not have sufficient testing available on a particular product to fend off the claims, especially novel forms of causation not yet addressed in the literature. A company's own product testing before litigation is ordinarily more than sufficient to demonstrate safety for regulatory and marketing purposes, but it may not be enough for the very different world of courtroom science.

A good study or series of studies can turn the tide against what some call "junk science," and even end the litigation. In the Bendectin cases, for instance, a series of animal and epidemiology studies in the 1970s and 1980s (at least one funded by Merrell Dow Pharmaceuticals, the maker of Bendectin) eventually generated a scientific consensus that Bendectin did not cause the alleged birth defects. The litigation fizzled over time because of these findings.

Similarly, early cases in which plaintiffs alleged their cancer was caused by exposure to electromagnetic fields died on the vine because the power industry had already conducted epidemiology studies showing no association. In our experience, defendant-sponsored state-of-the-art genetic testing in an agricultural-product birth-defect case recently formed the basis for a *Daubert* ruling excluding the plaintiffs' expert. The studies helped demonstrate that a child's health problems were caused by a genetic mutation.

Managing the competing concerns involved in company-sponsored testing is a difficult task. Let's walk through the decision process and look at some of the issues that arise.

Ask the Questions

• *Why testing?*

When should testing be considered? Start by asking the

question, On the balance of the existing science, can the plaintiffs survive a *Daubert*/*Frye* motion and get to trial? If the answer is yes, or even a strong maybe, testing should be considered, as it may be the only means to reverse the equation. Here are some additional questions to ask: Will the testing give conclusive answers on a critical issue? Will the test results likely be sufficiently clear and understandable to make a difference? Is the litigation vibrant enough to justify the risk of testing? Is there a way to beef up the existing science case without doing testing? Is there any independent research under way that would do the trick in lieu of company-sponsored testing?

If counsel believe the testing will be very beneficial, the next step is to weigh the benefits of the testing against the risks.

• *What is the likely outcome of the testing?*

To maintain the independence of the testing, the company cannot control or direct its outcome. Warning: Side effects of this reality include sleepless nights and ulcers. An adverse result, or even one that is sufficiently oblique to be interpreted as adverse by the other side, could well help resolve the case—but in the wrong way.

The company typically already has a solid basis for believing that the product is safe and will perform safely, because many products face extensive pre-marketing testing and regulatory approval before entering the stream of commerce. The litigation testing is thus usually needed to respond to speculative plaintiff theories, rather than to answer legitimate questions about safety. Even then, however, twists and quirks in a test result, even if explainable and not truly reflecting any risk, can still undermine the litigation. Imagine the credibility, for the plaintiff, of a study performed by the defendant that seems to support one of the plaintiff's positions. Counsel need to consult with the appropriate scientists to weigh carefully the possible outcomes before undertaking testing.

• *How can the company protect the independence of the testing?*

If the testing is not performed with reasonable independence, at best, neither the judge nor the jury will pay any attention to it. At worst, a good plaintiffs attorney could argue that the company manipulated the science, committed fraud, or violated court orders and ethics rules. So once a company decides to go ahead with testing, it should turn it over to the scientists and minimize attorney involvement and contact. This is very difficult for most attorneys. The best scenario is to carefully assess the likely outcome, hire very good people to do the work, ensure that the test is properly conceived and structured, and then let the ship sail. (The lawyers can watch from the shore with a good telescope.)

• *Should the testing be conducted under work-product protection?*

Some of the attorneys may argue that the studies should be conducted under work-product protection until the decision is made to use them in litigation. Litigation testing, at least initially, could be considered work product, because the testing is part of the attorney's defense of the case and reflects the attorney's mental processes. But in today's litigation environment, the assurance of a work-product claim is not enough, nor is it the end of the inquiry.

There are two potential problems. First, if the client decides not to use the test, the work-product claim may be subject to challenge if the test's existence is disclosed in discovery. Some courts may view the work-product claim, appropriately or not, as an attempt to hide "adverse" test results. Second, if the company uses the results in litigation, testing conducted under an initial cloak of work-product secrecy might carry implications that could impair its credibility. The plaintiff's attorney's angle could be, "Aha, you hid the testing until you were sure how it would come out."

On the other hand, work-product protection may be critical, for instance, in circumstances where companies might fear sabotage or interference during the experiment, or until the test is fully completed, to avoid piecemeal disclosures during the course of the testing. This is sometimes a close and difficult question that must be addressed on a case-by-case basis.

• *Who should oversee and conduct the testing?*

The likely choices here are fairly straightforward. Testing could be conducted by a company's own scientists; a company's testifying experts; a company's consulting, nontestifying experts; or an independent researcher, such as a university professor. Any of these might be appropriate under the right circumstances, but the wrong choice could ruin the test. The two foremost considerations are independence and an assurance that the test will be performed and interpreted properly. Of course, these goals may be in conflict. The company's own scientists, for instance, may be the world's foremost experts on the subject and the best-placed to do the work, but they will also face the greatest assault on their independence.

• *Should you publish or not?*

Ordinarily, it is a good idea to publish test results in a peer-reviewed journal. Peer review of an expert's methodology is one of the *Daubert* tests of reliability. The company can use the peer review of its own methodologies as a nice contrast to the plaintiffs' absence of peer-reviewed publications supporting their causation theory.

Publication, however, presents its own set of problems. How much control does the company exert over the article itself? Less is certainly more, from the standpoint of credibility and independence, but the lawyers may then have little or no say about what the expert writes. In addition, rejection of the article is always a possibility, and if that happens, you can be sure that the plaintiffs will attempt to exploit it. Once again, the key is to retain highly competent and litigation-experienced scientists who understand the publication and litigation processes.

It would be easy to add a half-dozen more considerations to the list, including communication with the expert, management of the file, and adopting and using regulatory testing for litigation purposes. This is a complicated and growing area, where the rules are not clear and there is the potential both for much good and much harm.

For those who have not yet faced this issue, prepare yourselves: Plaintiffs' increasingly inventive claims and funding of their own testing will force most defendants in product liability, environmental, and tort claims at some point to look to their own testing for a successful defense.

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