KAYE | SCHOLER

Assessing Litigation Risks Before It's Too Late

There is a well-known adage that "hindsight is 20/20." Often times, as we are in the midst of a litigation—and long-ago written company documents are being splashed across the screens in front of juries, and past decisions are being analyzed and questioned—that adage comes to mind. Faced with a multitude of "woulda-coulda-shouldas," we think about whether different decisions would have been made at the critical time if litigation issues had been fully considered as part of the analysis.

Risk audits—referred to here as litigation risk assessments—are designed to do just that. It is a way to put on a plaintiff's hat, to look at real time current data and try and predict just where the litigation risks lie. It would be wonderful if we could actually see ahead and know whether a product will *actually* end up in litigation, what injury will *actually* be at issue, and which documents will *actually* be selected by plaintiffs' counsel to show the jury. But risk assessments are not a guarantee. Rather, the process is one aimed at identification of risks, understanding the scope and nature of those risks, and determining whether any of those risks are in fact "reducible."

Defining Our Terms

In discussing a "litigation risk assessment" in this article, it is useful to define the type of assessment we are referring to. First, a risk assessment is *not* an evaluation of the clinical risks or benefits of a pharmaceutical product. While that process is critical—and indeed required under federal statute and guidelines—to the decision to develop and release a new product, it is not focused on the *litigation* risks associated with the drug.

"Risk assessments are a way to put on a plaintiff's hat, to look at real time current data and try and predict just where the litigation risks lie."

Second, a risk assessment is *not* a litigation early case assessment. An early case assessment is an evaluation of a lawsuit in the first months after filing to determine whether or not to settle early. Prudent litigation management requires an analysis of the merits of a particular claim and a decision whether it is practical to settle before engaging in protracted discovery, motion practice, and trial. In such an analysis, the critical questions to be asked include determining the value of the litigation, the risks associated with exposing the product to a public trial, the likelihood a trial (or settlement) will encourage others to file suit, and the impact of the jurisdiction in which the lawsuit is filed. The

About the Author

Lori Leskin is Partner and Co-Chair of the Product Liability group at Kaye Scholer. She is valued by her clients for her ability to successfully assess, strategize and implement unique solutions to their unique problems. Lori handles all aspects of litigation strategy for complex nationwide and multidistrict litigations involving a variety of products, including currently, the representation of Pfizer Inc as national counsel in its Hormone Therapy and Viagra® product liability litigations. Viewed as a leader in her field, Lori regularly authors, organizes, speaks and is referenced on a wide range of product liability litigation topics through numerous mediums. She can be reached at ***lori.leskin@kayescholer.com***

This article originally appeared in The American Bar Association's Section of Litigation Winter 2013 newsletter.

assessment may provide a litigation strategy decision tree that focuses on likely motion practice tactics, key witnesses, and settlement or possible verdict values.

On the other hand, a litigation risk assessment discussed here is not focused on the venue of the lawsuit, the costs or likely success of particular motions, or even the specific injury of a specific plaintiff. Moreover, a litigation early case assessment begins only once a claim has been made or, worse, a lawsuit has been filed, and then it is too late to implement some of the risk mitigation measures that may be identified through a risk assessment.

> ***"A litigation risk assessment discussed here is not focused on the venue of the lawsuit, the costs or likely success of particular motions, or even the specific injury of a specific plaintiff."***

Here, we discuss a risk assessment focused on the product and its labeling in order to identify and reduce areas for potential litigation in the future, and to help protect the product if and when litigation arises. It asks a company to do "due diligence," so to speak, on its own product to understand the potential risks associated with it and to determine if there are actions that can be taken to minimize those risks.

The Value of Litigation Risk Assessments

The legal bases for product liability lawsuits are varied and far-reaching. Tens of thousands of product liability cases are filed annually, including some as mass tort actions that may involve thousands of individuals as plaintiffs. These cases may receive significant attention from the media, especially when they concern widely sold products that allegedly harm many consumers. On the other hand, some products never face liability litigation. Or they face a handful of cases that are easily defended. But a single case can lead to negative media coverage of an injury, or a medical article can identify a new potential adverse event associated with a product and trigger new attorney advertising—leading to an avalanche of lawsuits or leading to nothing. Looking down the road, it is often impossible to know which way the dominoes will fall. The idea behind a litigation risk assessment is to apply what we do know about litigation focal points now to help predict—and indeed guide—that chain of events.

Again, a litigation risk assessment does not guarantee a product will never face litigation, or that the company would prevail in litigation. But a strong label may encourage safer use of the product, resulting in fewer avoidable adverse events. Further, a strong label may deter plaintiffs—and, more importantly, plaintiffs' counsel—from filing lawsuits if and when an injury occurs. Or, the label may be more defendable in litigation if suit is filed. Better internal documentation also allows your litigation defense team the ability to defend against cherry-picking of "bad documents." (The concept of better documentation is discussed further below.) In other words, the litigation risk assessment seeks to uncover, and address, potential weaknesses in the product's defense *prior* to the initiation of any litigation.

Despite the certain benefits of litigation risk assessments, it appears that many companies do not conduct such an analysis in preparing to bring their products to market. In preparing this article, we questioned a small sampling of in-house counsel and found that most are simply unfamiliar with the process. This is unfortunate, however, as outside counsel involved in risk assessments have noticed an effect on litigation because of the stronger label and decreased risk involved in the product. These effects include a reduction in the number of lawsuits brought over a product, the duration of any lawsuits that were brought, an increase in the number of dismissals, and—perhaps most importantly—a reduction in the total legal spend required by a product. Thus, the investment made in a product *prior* to its introduction has identifiable monetary benefits down the road.

> ***"Outside counsel involved in risk assessments have noticed an effect on litigation because of the stronger label and decreased risk involved in the product."***

Getting Started

So when is the best time to conduct a litigation risk assessment? Generally, it is best when there is still an opportunity to make changes to the labeling or other documentation—and before the product is released generally to the public. However, this does not mean that existing products are immune from an assessment—just as they are not immune from litigation—particularly if medical literature or a cluster of new adverse event reports raise the prospect of newly identified risks.

The extent of the analysis, and the actions taken in response, depend on just how great the risk is perceived to be. Thus, the first step to be undertaken once it is decided that a risk assessment should be conducted is to set the parameters of the assessment itself. How many witnesses will you interview? How many documents will be collected? These decisions should be based on the consideration of several factors, including:

- Is the population expected to use the drug a large population? A "special" population (i.e., children, pregnant women)?
- Is it likely that the drug will be prescribed for off-label uses?
- Is the medication intended to be used chronically?
- Is there a known serious adverse risk already associated with use? Have deaths or other serious adverse events from studies been flagged as matters of concern during the clinical trials?
- Have studies of other products in the same class reported serious adverse events? Has a boxed warning been added to any product in the same class? Have any products in the class been withdrawn for safety-related or efficacy reasons?
- Are the warnings different in the United States versus in Europe?

The scope of the assessment should then be calibrated to the level of scrutiny warranted by the product based on answers to these questions and others. In other words, the "riskier" a product on its face, the more intense inquiry it should undergo. Thus, a product expected to be used by a large population warrants a higher level of investigation than one being used by a narrow population; and medications where serious adverse events have already been reported may warrant a more in-depth assessment than ones with no adverse events reported during clinical trials. Indeed, our discussions with counsel regularly performing such assessments cite reported injuries during clinical trials as the most important factor in determining whether to conduct a risk assessment for a product.

> ***"The 'riskier' a product on its face, the more intense inquiry it should undergo."***

Conducting the Assessment

Once the level of inquiry is agreed upon, a team can be assigned to conduct the audit. Product liability issues pose unique and dangerous risks to a product and a company. These are not areas that can, or should, be handled exclusively by a junior lawyer, a non-litigator, or a commercial executive. Even experts experienced in scientific risk-benefit analyses for purposes of drug approval and safety management may fail to accurately identify all of the nuances of product liability law that present themselves in a product's litigation risk profile. These areas of law require consultation with experienced products liability litigators who have spent years analyzing, scrutinizing, and counseling clients on these issues.

The actual assessment will include:

- interviews of personnel in key areas, including scientific and clinical research, regulatory, and marketing/commercial;
- document review, including of the core label, clinical trial reports, FDA correspondence, and risk management plans;
- review of the published literature sufficient to understand the underlying medical condition being treated, the class of medications into which the new drug falls, and the etiology of any serious adverse events that were reported during clinical studies.
- additional steps may be taken depending on initial review and risk calibration.

Reporting Results

Once concluded, the findings of the assessment must, of course, be shared. The first audience should be in-house counsel. After the initial report and discussion of the findings, reports to a wider audience may be made as necessary. It should be obvious, though, that in making any such report, care must be taken to protect the privilege. The risk assessment itself should never be subject to future discovery.

The report of the litigation risk assessment should share observations regarding potential litigation risk, but it should also put that risk in the appropriate context. It is easy to say simply "You have a risk of being sued," but such advice provides nothing of use. Rather, some effort must be made to identify specific areas where a product may be at particular risk, and why, and—most importantly—specific ways to reduce that risk. Importantly, the significance of the risk—for example, the potential population impacted, the severity of adverse event identified—should be weighed against the modifications being proposed.

> ***"After the initial report and discussion of the findings, reports to a wider audience may be made as necessary. It should be obvious, though, that in making any such report, care must be taken to protect the privilege."***

Proposed risk management and mitigation actions may include, as necessary, changes in labeling, modifications to the company's pharmacovigilance plan, or simply clarification of internal documentation surrounding the decision-making process. In our discussions, the modification recommended most often—both by inside and outside counsel—was a change to the label.

Ultimately, the client has to weigh the risks and benefits and decide how best to proceed. Follow-up meetings with business personnel may be scheduled based on the level of risk identified and the actions needed to address those risks to help implement the changes to be made.

Write Right

A significant part of the risk assessment process—and often the risk mitigation recommendations as well—focuses on the creation and clarification of documents created as part of the product's development. Much of the effort that goes into post-assessment work may be avoided through effective document management throughout the process.

"Hot documents" are a plaintiffs' counsel's dream. Nothing is more powerful at trial than a company's own internal documents used against it. Plaintiffs' counsel blow up images of them on screens during openings and closings and at every opportunity during trial. They are hard evidence that can be handled, read, and reread by a jury. Company witnesses are cross-examined with them and are forced to try and explain—often unsuccessfully—a document they didn't write and likely never saw before litigation. In court, every document—whether hard copy or electronic, whether a formal memo or a quick email—is fair game.

> ***"Nothing is more powerful at trial than a company's own internal documents used against it."***

Thus, it is important that company employees are trained on how to write and create documents early on in their careers. It is important, too, however, that litigation concerns not serve as a block to true scientific discussion and that employees not be—or feel—discouraged from expressing actual concerns

or discussing factual information for fear of litigation. This is not a matter of "covering up" bad information. Rather, the focus in document training is on the creation of accurate documents; it is about injecting thoughtful, common sense discipline into internal corporate writing to avoid the unintended consequences that flow from speculative, inaccurate, or insensitive language. Employees must be taught to think carefully before generating documents, and they must understand the potential harmful consequences their written words can have on the company.

Thus, employees should understand there are certain guidelines that should be followed in preparing documents. These include:

- First and foremost, any document should be created with the assumption that it will be produced in litigation.
- The document should say what the writer means, and the writer should make sure he or she means what document says.
- Avoid loose, imprecise, and vague language. This is particularly true in circumstances where certain words are a term of art.
- Avoid documenting personal opinions, particularly ones that are not within an employee's particular expertise—keep to the facts.
- Avoid the use of slang, exaggeration, sarcasm, or inflammatory language that could easily be quoted out of context.

It is also important to teach employees to be smart in document distribution. Keep distribution lists to a minimum and only include those people necessary. Consider ways that preliminary conversations to discuss issues can be held in person or telephonically. This can permit the free exchange of ideas, the elimination of ones that are wrong or unfounded, and the reaching of a consensus without creating the flurry of emails or memos early in the process. Privileged documents—seeking legal advice from the in-house or outside legal department—should be identified as such.

> ***"Much of the effort that goes into post-assessment work may be avoided through effective document management throughout the process."***

Finally, convey to the business personnel making decisions the need to close the loop. Once a decision is made, a closing memo should be created that explains factually the process that was undertaken and the reasons supporting the decision (and why other courses of action were rejected). Similarly, if a document (such as an email) is created that can be read out of context, or which raises an issue that is later dealt with, a responsive answering memo should be created as well. It may be that these open

issues are only identified as a result of the risk assessment, which is yet another reason why such an assessment should be done.

Again, the goal is not to eliminate or simply reduce documentation. In litigation, the *absence*of documentation may be just as bad—if not worse—than poorly worded documents. A lack of adequate documentation may suggest that a particular decision was not thought through carefully. Further, simply reducing the number of documents eliminates the availability of*good* documents which can be used in litigation to support the decision-making process, and which could prove crucial in explaining the company's conduct. Rather, any documents should accurately reflect the Company's analysis, motives, and decision making, and the Company's efforts to do the right thing.

> ***"In litigation, the* absence*of documentation may be just as bad—if not worse—than poorly worded documents."***

Preparation Is Key

Risk management is both an active and reactive process. The analysis suggested here can most certainly be conducted by a litigation defense team, after litigation arises. However, at that point, the decisions made by the company are already being evaluated by plaintiffs' counsel, a judge, and a jury. The ability to explain poorly written documents, adverse events reported in clinical trials but not included on labels, or published medical literature becomes limited if the issues were not addressed at the time they initially arose. The effort taken now to look forward and potentially reduce identifiable risks can protect against the need to watch a jury later and think, "If only we had ..."

Hindsight may be 20/20 but, as another old adage goes: By failing to prepare, you are preparing to fail.