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Going Back to Risk Basics for Clinical Work: Beware of Overly Broad Indemnification Clauses, Lack of Clarity on Third-Party Loss Clauses, and Incomplete Insurance Coverages

By Blaine Templeman and Sarah E. Aberg

1. You May Get What You Drafted.

Broad indemnification provisions, once played out, can sometimes result in surprising applications. For example, in *Mass Transit Administration v. CSX Transportation, Inc.*, 708 A.2d 298 (Md. 1998), the court considered an indemnification clause in a procurement contract between the Maryland Transit Authority (MTA) and CSX Transportation, Inc. (CSX). CSX had contracted with the MTA to operate a commuter rail service between Washington, D.C., and Baltimore. In the contract, the MTA agreed to "indemnify, save harmless, and defend CSX from any and all casualty losses, claims, suits, damages or liability of every kind arising out of the Contract Service." Ultimately, the court found that CSX, whose train had crashed into a piece of equipment belonging to CSX's own subcontractor, could be indemnified against the subcontractor's claims by virtue of the "any and all" language in the indemnification clause between CSX and the MTA. This was because the services the subcontractor was performing were part of the services CSX had contracted with the MTA to provide under the services contract.

While some courts will find a way to avoid results like that reached in *Mass Transit Administration v. CSX Transportation, Inc.* (usually by voiding the outcome based on the fact there was no regard for the factual determination of liability, *see PIC Group, Inc. v. Landcoast Insulation, Inc.*, No. 09-662, *9 (S.D. Miss. Sept. 1, 2010) (citing cases)), this is not always the case.

When constructing an indemnification clause in a clinical trial agreement, master agreement with a CRO, or a master manufacturing agreement, avoid rolling out the standard language prior to thinking through the deal very carefully. Ask yourself several questions:

- Does the drug involved pose any special safety or administrative concerns?

- Is there any special IP risk?

- What part of the services will be subcontracted? How wide and far will the indemnification flow? Will subcontractors be providing indemnification for all parties working on the project?

- Is very broad indemnification appropriate or would a series of more specific indemnifications be a better approach?

- What will the consequences be if the service provider does not perform? What provisions could be used to specifically identify that risk?

These sorts of questions should help you tailor an indemnification provision that makes sense for your transaction. Also, keep in mind that most indemnification provisions apply only to third party losses, so read the next part of this blog to make sure you are being clear on the types of losses that your provision intends to cover.

2. What Losses Will Your Indemnification Cover?

Several states presumptively apply indemnification provisions *only* to third-party claims, and will not apply the provisions to claims involving the two parties to the contract absent unmistakable clear language to that effect. *Hooper Assocs., Ltd. v. AGS Computers, Inc*., 74 N.Y.2d 487, 492-93 (1989). This requirement is often strictly enforced by the courts. Even "when an indemnification provision contains clauses that the court considers to be inapplicable to suits between parties–such as requiring that notice of a claim be given to the indemnitor or allowing the indemnitor to assume the indemnitee's defense–courts have concluded that the contract does not evidence an unmistakably clear intent to indemnify attorneys' fees incurred in a lawsuit between the contracting parties." *Goshawk Dedicated Ltd. v. Bank of New York*, 2010 WL 1029547, at *6 (S.D.N.Y. Mar 15, 2010) (citing cases). So, if you want the indemnification to apply to more than third party losses, it is time to turn on "Caps Lock," hit "Return," get out the bold lettering, and add a sentence that makes the intent of the parties clear.

3. When Did You Last Talk to Your Broker?

Clinical trial injury poses a serious financial risk for all of the parties to a clinical trial. For the patient, injury from participation in a clinical trial may be serious (requiring long term care) or may even result in death. And all this can be expensive. Doctors and hospitals generally rely on the sponsor to get the right insurance, but insurance may not cover all the costs and insurance will certainly not insulate the doctor and hospital from suits and other actions. Very few clinical trial sponsors realize that their insurance does not always cover all of the costs for treatment of clinical trial injury. Even a sophisticated company may not understand the terms of coverage spelled out in its insurance policies and the risks associated with relying on it, including the fact that a sponsor often must come out of pocket to pay such costs even if they have already covered a high retention (deductible). Coverage under some policies will not even kick in until an injured patient threatens to bring a suit.

When the parties to a clinical trial agreement agree on a provision that requires a sponsor to maintain insurance that covers *all of the potential liabilities arising in connection with a clinical trial*, it is possible that very little has been achieved. This sort of language requires insurance that will never be written by any U.S. insurer. So, the parties may be taking false comfort in its belief that the sponsor and its insurer have such insurance and the sponsor (and not the hospital) will take care of everything.

Before initiating a clinical trial, take time to consider carefully all the coverages that will address the risks of trials – the insurance held by the drug manufacturer, the PI's insurance, the study site's insurance, and the sponsor's insurance. The goal should be to make sure they all work together to protect all the parties involved – including the study subject.

In a future blog, we will cover some of the issues of insuring a non-U.S. trial.

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