San Diego Daily Transcript

Limiting Liability in Clinical Trials: Non-Lawyers, Lawyers Beware

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March 26, 2009

Clinical trials are the lifeblood of biotech. Finding the right service providers (CROs, safety, IVRS, consultants, contract manufacturers and many others), as well as the right clinical investigators and sites, results in a complex web of legal obligations and potential liabilities. Limitation of liability clauses can reduce a party's exposure if a contractual obligation is breached. More often, limitations of liability provisions are used to shift risk to the sponsor of the clinical trial. But, if your contracts are well negotiated and drafted, the risks can be carefully and fairly allocated between the parties in a balanced and reasonable manner. Because of the complexity of the legal relationships and liabilities found in clinical trials, this article is limited to a brief description of limitation of liability clauses, and their general strengths and weaknesses.

At its most basic, a limitation of liability clause is simply a provision that limits the amount and type of damages one party can recover from another. Such limitations can be quantitative, qualitative or both. A quantitative limitation of liability clause caps one party's potential liability to a determinable amount. For example, $500,000, two times the contract price, or the amount paid under the contract.

Additionally, a limitation may be qualitative. A qualitative limitation of liability clause might limit potential liability to specific types of damages or claims. Thus, a clause may limit liability to direct damages (damages that are the natural and ordinary result of the breach or action -- sometimes called general damages), and prohibit the recovery of indirect damages (damages that, while not immediate, were reasonably contemplated by the parties as a result of the breach or action, e.g., lost profits or business, sometimes called consequential or special damages). Qualitative clauses may also limit damages for specific claims, such as breach of contract, failure to deliver timely results and negligence.

When negotiating a limitation of liability clause, it behooves a party to consider the services offered and the potential exposure risked. For example, when a biotech company contracts with a contract manufacturer for the development of novel formulations of the biotech's product, the contract manufacturer will likely seek to limit its potential liability for future uses of the product unrelated to

the manufacturer's work. At the same time, the biotech company will want to assure the contract does not release the contract manufacturer from losses stemming from contamination the manufacturer might introduce into the manufacturing process. In another scenario, a CRO will typically try to limit its potential losses for any consequential damages. Such a provision should be the subject of careful consideration and much discussion. A complete or absolute limitation on all consequential damages should not be agreed to lightly.

Unfortunately, many see limitations of liability provisions as nothing more than legalese. But, failure to carefully construct a limitation -- for instance, failing to be specific -- can result in the clause having little or no effect. Furthermore, simply using a clause that contains only a broad, general limitation on liability may be read to apply only to claims for breach of contract and not for negligence. Accordingly, "express and unequivocal language in the agreement" is the best way to assure that a limitation of liability clause will not only be upheld, but also be given the effect intended. Indeed, an agreement that clearly specifies a damage amount for a specific cause of action is likely to be upheld against that cause of action, even where damages are more than 1,000 times above the contractual limit.

While powerful, limitation of liability clauses are not silver bullets. For example, they might not protect a party against its own intentional conduct (other than intentionally refusing to perform the agreement), nor protect a party from claims of fraud or misrepresentation. And, because limitations of liability clauses are contractual, they do not apply to third parties that have not signed the agreement. Thus, a licensor of a molecule or sponsor of a clinical trial cannot use a limitation of liability clause to avoid liability for a claim from an injured patient if it is sued directly. This would require an indemnification provision by the licensor or site administering the treatment. However, a specific limitation of liability clause may be successful in protecting a licensor or sponsor against claims seeking contribution from the licensee or site.

Limitations on liability clauses require careful consideration of the type of liability a party is likely to face and the significance of the exposure. Making the situation more difficult, there are a multitude of different relationships in clinical trials (e.g., sponsor-CRO; sponsor and/or CRO-investigative site; sponsor-patient; investigative site-patient), which carry different obligations with exposure to different risks. Given this complexity, counsel negotiating such provisions must be intimately familiar with the clinical trial process, the client's goals and the risks the client is willing to accept.

For more information on use of limitation of liability clauses (and other legal matters affecting the life sciences industry), contact the authors of this article. Sheppard Mullin will host a Life Sciences Summit, "Opportunities for Challenging Times," on March 31 in its Del Mar office, at 12275 El Camino Real, Suite 200, San Diego, CA 92130. Visit sheppardmullin.com/events-157.html for more details.

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