



RISK NOTE

SUBJECT: Insurance in Clinical Trials

In the spring of 1997, the Health Care Protection Program (through the former BC Healthcare Risk Management Society) published a document titled Guidelines for Risk Management and Liability Control in Clinical Trial Research in B.C.'s Health Care Facilities (the "Guidelines"). Since that time, many things have changed in the world of clinical research. Landmark product liability lawsuits against pharmaceutical companies such as Merck & Co for their arthritis drug Vioxx have showcased the risks and responsibilities of every party in a clinical trial study. At the same time, a more restrictive insurance market has emerged following the devastating effects of world events such as 9/11 and extreme weather catastrophes making it more difficult for parties to arrange insurance to protect their legal interests.

The purpose of this Risk Note is to update the Sponsor Coverage Limits and Recommended Insurance Coverages (Section 5.3, Page 28) in the Guidelines.

To manage potential liability exposures associated with participating in clinical trials, health care facilities should at a minimum, ensure they are fully indemnified by the sponsor for their participation. Adequate insurance of the sponsor is essential to financially back the indemnity that is obtained. This update relates to the insurance requirements of the sponsor.

To fully appreciate the significance of the sponsor having proper insurance it is important to understand the common law rule of joint and several liability, sometimes called the "deep pocket rule" or the "1% rule". This rule makes each and every defendant in a tort lawsuit liable for the entire amount of the plaintiff's damages regardless of the defendants' relative degree of fault or responsibility. A co-defendants' inability to pay could find the defendant with the "deep pockets" paying 100% of the damages when they are as little as 1% responsible for them. A sponsor should be able to indemnify the health care agency and be financially capable of meeting the responsibilities arising from its own negligence. A sponsor's failure to meet those responsibilities could prove very costly for the health care agency.

The original Guidelines recommended that the level of insurance or self-insurance limits for third party sponsors should be \$10,000,000 per occurrence for smaller pharmaceutical companies and \$50,000,000 per occurrence for larger companies. We have found these insurance limits are unrealistic in today's insurance market, however, the risks of doing research are high and there are reasons why the commercial insurance market (with its inherent focus on profit) is reluctant to entertain certain classes of insurance risks:

- Clinical trials involving children, for example, are viewed as being high risk. Children are obviously a vulnerable group for research. Research, particularly that which poses moderate or substantial risks to participants with no potential for direct benefit, should be performed very cautiously on children. Some insurance companies will not insure any pharmaceutical companies for clinical trials that involve children;
- Clinical trials involving healthy participants, as opposed to those whose health is compromised, are also a red flag to insurers. The potential for damages (in pain and suffering, medical expenses and loss of future income) is greater when the plaintiff can allege that they were in good health before they participated in the trial;
- A sponsor's inability to obtain insurance may also be a reflection of the insurance company's impression that the sponsor does not have sufficient experience or expertise in a particular area. Generally, an insurance company's underwriting process will involve obtaining details on the number of years that a company has been in business. A sponsor that is not well-established may have difficulty obtaining insurance;
- Another area where insurance companies have made changes to protect themselves against unprofitable results is with the introduction of aggregate limits of insurance. An aggregate limit means that the most the insurer will pay within the policy period is the limit stated as the aggregate on the policy, irrespective of how many claims are made against it. The result is that the limit of insurance could be eroded by previous losses. This is a concern when a pharmaceutical company has one policy which covers their participation in multiple trials with multiple products and involving many participants. When faced with a class action lawsuit involving hundreds of plaintiffs, just how much protection will such insurance really provide?;
- To further complicate the matter, professional liability insurance such as that which covers the sponsors for the part of their operations involving testing on human subjects is written on a "claims made basis". This means that claims must be discovered and reported within the policy period to be covered. Sometimes it may take years before the damage that a drug has caused is discovered. This could mean that damage stemming from the downstream

- products liability is not insured because the period of the policy has lapsed before such damage has manifested itself.

All of these factors combine to make insurance in clinical trials a confusing and complex issue. Health care agencies want to participate in research and yet they want to protect themselves and their assets from loss at the same time. Reconciling the risks with the opportunities is a challenge.

To manage potential liability exposures associated with participating in clinical trials a health care agency's best defense is to:

- materially adhere to the sponsor's protocol;
- administer the medical care in accordance with generally accepted standards; and
- comply with all appropriate laws and regulations governing research.

For those risks of the clinical trial that are outside the health care agency's control they should ensure that they are fully indemnified for their participation. The importance of this cannot be over-stated.

The level of insurance or self insurance limits recommended for third party sponsors is as follows. Such limits are recommended in order to financially back the indemnity the sponsor grants and thereby limit the risks of principal investigators, the health care agency and associated parties (i.e. directors, officers, employees, agents etc.):

"The Sponsor shall procure and maintain, at its sole expense, policies of general liability insurance in the amounts of not less than \$10,000,000 per occurrence, \$10,000,000 aggregate naming the indemnitees as additional insureds. Such insurance shall include clinical trial liability, broad form contractual liability to back the Sponsor's indemnification and shall also provide product liability coverage. The obligation to maintain the insurance shall survive the completion or early termination of this Agreement. If any such insurance is on a claims-made basis and that insurance is cancelled or not-renewed, it must contain at least a 24 month extended reporting period."

Evidence of appropriate insurance should be obtained from the sponsors in the form of an insurance certificate. The insurance certificates must be read carefully to ensure that the required extensions are actually included. The certificate should specifically state that the coverage contains clinical trials liability, products liability, broad form contractual liability and includes the indemnitees as additional insureds. If the certificate does not state this, then these extensions may not be part of the coverage.

While the above language recommends an insurance limit of \$10,000,000, in some cases limits of \$5,000,000 per occurrence and/or \$5,000,000 aggregate are the most that is available or reasonably affordable. This is often driven by the insurance market that may be unwilling to provide higher limits to smaller pharmaceutical companies.

If the risks of the trial are considered low (i.e. later phase, non-invasive, not on children, not on healthy subjects) then a \$5,000,000 limit may be sufficient. On the other hand, if the risks of the trial are higher and \$5,000,000 is the highest limit of insurance available, the health care agency should carefully assess the risks in relation to the opportunities of participating in that particular trial. The health care agency should document the reasons for accepting less than \$10,000,000 limits.

We do not recommend accepting limits of **less than** \$5,000,000 under any circumstances if the trial involves testing on human subjects. Some bio-tech companies carry as little as \$1,000,000 or \$2,000,000 in liability insurance. The business of pharmaceutical research is extremely risky and, in our opinion, limits such as this are insufficient for the exposures.

Finally, the amount of insurance is not a limit on the indemnification obligations of the sponsor. Insurance provides evidence of the ability to pay. If a sponsor clearly has the ability to pay substantial legal costs and damage awards notwithstanding the limit of insurance then \$5,000,000 (or less) may be acceptable. Very large pharmaceutical companies such as Bayer and Johnson & Johnson would be liable to the full extent of their sizable assets.

Summary: The critical requirements for proper indemnification and insurance language in order to adequately transfer and pay for risk have been emphasized in this Risk Note. This is an update to Section 5.0 of the Guidelines and should be referenced in conjunction with the Guidelines. Insurance and indemnification are at the core of adequate protection from liability risk in clinical trials.

If you have any questions about indemnity and insurance provisions related to clinical trials, please contact HCPP.

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It should be clearly understood that this document and the information contained within is not legal advice and is provided for guidance from a risk management perspective only. It is not intended as a comprehensive or exhaustive review of the law and readers are advised to seek independent legal advice where appropriate. If you have any questions about the content of this Risk Note please contact your organization's risk manager or chief risk officer to discuss.