Clinical Trials Liability: The Hidden Risks

WAYNE CLIFTON

Wayne Clifton is director of product development at CIGNA Property & Casualty, Philadelphia, PA 19192. The views expressed here are the author's own and not necessarily those of Bio/Technology.

Once through the gauntlet of scientific and ordinary hazards of biotech research and development, firms involved in clinical trials, still years away from selling a product in the general marketplace, run the risk of product liability suits for injury to test subjects. These firms must be prepared to deal with random adverse events that could affect their business. Beyond the usual difficulties of litigation, biotech firms face public fears about substances that threaten health and courtroom challenges created by dueling expert witnesses. Knowledgeable insurers can help your biotech firm formulate good clinical practices, good laboratory practices, and good manufacturing practices. A knowledgeable insurer can also help you develop informed consent documents that can protect your interests should a serious accident occur. If injury does occur, such insurers will be sensitive to the expertise of potential witnesses and the potential assistance that the defendants themselves can offer.

As most biotech company executives know, anyone can be sued for anything at any time. You, as the company, can get sued if the plaintiffs even think that they *might* recover damages. But if you practice specific risk management techniques, you have a greater chance of successfully defending yourself against negligence allegations, given that you practice standards of care, conduct your research appropriately, and carefully prepare your product with warnings and instructions.

During the clinical trials process every company's goal should be to protect subjects from *unforeseen* risks. This is done by complying with Food and Drug Administration (Bethesda, MD) regulations, by developing an effective monitoring program for clinical trials, and by developing comprehensive informed consent procedures. With so many crucial things to worry about while you're still conducting your company's critical research, it makes sense to leave your insurance risks to experts who specialize in your industry.

A biotechnology insurance specialist should offer product liability coverage for drugs in clinical trials. Product liability should explicitly provide coverage for bodily injury or property damage resulting from your firm's negligence in selecting or monitoring a contract research organization or principal investigator, as well from negligence concerning the products themselves. This will fulfill your requirement to the institutions in which your trials are conducted that you carry sufficient product liability insurance. Your coverage should also include drugs that evolve into investigational new drug treatments. This frees you from having to worry about risks associated with the continued supply of drugs to patients for compassionate reasons while those drugs are still in clinical trials.

One policy should cover multiple clinical trials, which will reduce your administrative costs and workload. Where permitted by law, it should automatically include coverage for punitive damages to help you survive extraordinary payments made as the result of a court ruling.

Speaking of costs, extremely large phase III populations don't have to have a devastating impact on your bottom line. A quality insurance company can estimate your annual premium, for the length of the protocol, through a cost control program. This will help you forecast yearly expenses and total program costs. If you are dealing with a specialized insurer, your rate should vary by test phase, and should take into consideration the illness being treated, the existence of alternative treatments, and whether the same drug has been in clinical trials before. Graduated rates should be provided for each phase, so that as the subject base gets larger, your premiums don't increase proportionately.

A specialist should also have other customized coverages available: For example, you should be able to vary the length of time for maintaining clinical trial coverage after the completion of phase III. Such an option will also help you manage cost versus perceived risks.

To help identify and manage risks, be sure your insurer has experienced risk management and loss control specialists to assist you through all of your trials and tribulations. A good loss-control specialist can perform consulting services while preclinical studies are still in progress to help minimize risks both *before* clinical trials begin and while they are taking place. Claims specialists should be trained in biotechnology principles and claims handling for your property, business operations, and products.

A specialized insurance program could help your company to anticipate, and mitigate, damages should an accident occur. Your firm's reputation, long-term costs, and possibly even its ability to market an approved drug, may depend on coverage, loss control, and claims handling. Protect your trade secrets, new product developments, and clinical trials by insuring with a quality insurance carrier. You can reap the benefits of a comprehensive risk management program, and in the event that unfortunate loss, damage, or injury does occur, you will receive prompt and professional action on your claims. ///