

Clinical Trial Injuries

Will Your Client Lose His/Her Medical Practice?

Part One of Two-Part Article.

By Norman M. Goldfarb

The plaintiff's bar has discovered an opportunity in clinical research. The deep pockets of pharmaceutical companies provide one attraction, but attorneys are seldom shy about suing anyone who might even remotely be found liable for an injury. Successful litigation is rare, but the judgments can be expensive. Because of this, many physicians who conduct clinical research are reviewing their medical malpractice insurance policies. Many others, however, have no concept of the looming risks and of whether they are protected by their medical malpractice insurance policies when taking part in clinical trials.

WHAT DOES YOUR INSURANCE COVER?

The courts (for example, *Heinrich v. Sweet*, 62F. Supp.2d 282, 313 (D.Mass. 1999)) generally regard clinical research injuries as regular medical injuries, but medical malpractice policies are often ambiguous on the topic of clinical research. They may refer to coverage for "medical care," which, strictly speaking, clinical research generally is not. People in clinical trials are not "patients"; they are "subjects," "volunteers" or "participants." Sometimes, unapproved drugs and devices or clinical research are specifically excluded from coverage. The investigator may be able to purchase a clinical research rider on the policy, but often not.

Pharmaceutical companies that sponsor clinical trials generally do not call attention to this issue, except by sometimes requiring medical malpractice insurance in the clinical trial agreement. (Required coverage limits are usually \$1 million per incident and \$3 million in aggregate.) Sometimes, they will ask for a certificate of insurance, or the right to obtain one on request. (Occasionally, they require general property and liability insurance and not medical malpractice insurance, which probably reflects a contract that has been adapted from a different area of business.) Because many investigators never read the clinical trial agreement, they will miss these "fine points."

Health insurance companies generally cover the cost of treating subject injuries, but they, too, are becoming more aware of their exposure to clinical research risks. There is an ongoing debate in the clinical research industry about who should pay for this treatment. On the one hand, there is evidence that clinical research does not increase, and might even decrease, direct costs to insurance carriers. In addition, new treatments proven in clinical trials keep people healthier, reducing insurance carrier costs or at least performing a valuable public service. On the other hand, it is not entirely clear why insurance companies and their customers should subsidize clinical trials for highly-profitable pharmaceutical companies. Also, subjects who make health insurance claims may hit their policy limits; their premiums may increase; and, if they subsequently lose their jobs, new coverage may be expensive and difficult to find.

Unfortunately, injured subjects sometimes want more than free repairs. A few carriers offer special clinical research malpractice insurance, but it is prohibitively expensive for part-time investigators. One bright spot is that hospitals and clinics that perform a lot of clinical research usually have professional risk managers and adequate insurance coverage, subject to the discussion below. (Note, however, that it generally covers only activities on their premises.)

WHAT MAY BE MISSING IN THE CONTRACT

Clinical trial agreements generally indemnify clinical investigators for problems with the study drug, but never for the investigator's negligence. Most indemnification clauses contain loopholes. For example: 1) Injuries caused by study procedures often are not covered; 2) Injuries prior to randomization — in other words, during the screening process — may not be covered; 3) Even 1% contributory negligence by the investigator may void the indemnification, as may an unrelated deviation from the protocol on *another* subject; and 4) Prior written authorization may be required to charge the sponsor for treatment.

OTHER AREAS FOR POSSIBLE LIABILITY

The plaintiff's bar has been exploring causes of action beyond physical injury that would not be covered by medical malpractice insurance. One class action lawsuit, *Diaz v. Hillsborough County Hospital Authority*, for example, was settled in 2003 for \$3.8 million for "dignitary harm." Dignitary harm occurs when clinical trial subjects are not treated with respect

for their personal rights. In the *Diaz* case, the plaintiffs alleged that they were induced by a very defective informed consent process to participate in clinical research that involved risky and painful procedures, although no long-term bodily injury resulted. Although this case remains an anomaly, the U.S. Supreme Court has stated that “No right is held more sacred or is more carefully guarded by the common law, than the right of every individual to the possession and control of his own person, free from all restraint or interference of another.” (*Cruzan v. Director, Missouri Department of Health*, 497 U.S. 261, (1990))

It is only a matter of time before a subject attempts to file a claim under HIPAA for damages related to harmful disclosure of personal health information. With the growth of medical genetics, genetic information such as DNA sequences will continue to increase in commercial value. (Because a big enough piece of DNA intrinsically identifies the donor, HIPAA may come into play here as well.)

As in other potentially lucrative legal fields, such as regular medical malpractice, the clinical trial plaintiff's bar becomes more effective over time, learning from successes and failures, sharing documents, and setting precedents. One upcoming cause of action is likely to be based on an FDA regulation that says “the information that is given to the subject or the representative shall be in language understandable to the subject or the representative.” The industry has left itself wide open by writing many (most?) informed consent forms at a 10th-

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grade, 12th-grade or even higher reading level. In addition, most informed consent forms are littered with undefined medical jargon on topics such as side-effects. It would be child's play for a plaintiff's attorney to prove that his/her client reads at, say, the 8th-grade level. The judge may then throw out the written informed consent form and challenge the defendant to prove that the verbal informed consent process was adequate.

SHIFTING LIABILITY

Most pharmaceutical companies are aware of these growing risks. They have every right to protect themselves from incompetent and negligent investigators. Clinical trial agreements are therefore evolving, usually to prevent the transfer of risk from the investigator to the study sponsor. Indemnification clauses are likely to become more porous. Cross-indemnification clauses — by which the investigator indemnifies the sponsor for harm caused by the investigator — are likely to become more common and comprehensive.

The principle of symmetry suggests that if it makes sense for the sponsor to indemnify the investigator, then it also makes sense for the investigator to indemnify the sponsor. In either case, the indemnification is for damages caused by the indemnifying party, so why shouldn't the guilty investigator indemnify the innocent sponsor? There are at least five good reasons that may apply in specific circumstances:

To start with, there may not be a guilty party, or one that deserves 100% of the responsibility. Indemnification defines who pays the defense costs until responsibility is apportioned at the end. Consider the scenario, for example, where the investigator has indemnified the sponsor, pays all the defense costs (which can easily exceed \$1 million), and wins the case. The sponsor has no obligation to reimburse the investigator for part of those costs.

- In most cases, the study subject

would not have been injured in the absence of the study.

- Medical malpractice insurance seldom, if ever, covers costs associated with cross-indemnification.
- The risk-reward profiles of the two parties are far from symmetrical: Pharmaceutical companies conduct clinical trials with the expectation that they will earn millions of dollars in profit from a successfully marketed drug; investigators may earn only a few thousand dollars from a study, and quite possibly lose money.

Pharmaceutical companies can spread their legal costs and judgments over a portfolio of drugs. Even with perfectly safe medications, they expect a certain number of injury claims from an active clinical research program. They therefore buy insurance, or self-insure to cover the very small percentage of subjects who press expensive claims. In contrast, most investigators never see litigation from a study subject; putting \$50 per subject into a litigation reserve doesn't make a lot of sense.

One malpractice case can drive an investigator out of the research business, and can even destroy his or her medical practice or force personal bankruptcy. (A good malpractice insurance policy mitigates but does not eliminate these risks, and may not be renewed.) Government entities such as state university hospitals are legally prohibited from indemnifying sponsors. If sponsors are willing to do business with them on that basis, they can do the same for private-sector investigators.

Next month, we look at ways investigators can protect themselves.



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