

## Good Clinical Practice Q&A: Focus on Sponsor Liability

### **Under what theories might sponsors of clinical trials be liable to participants in clinical trials?**

The sponsor of a clinical trial has responsibilities related to its role as "overseer." That said, the sponsor may transfer its obligations by written agreement to a contract research organization. Regardless of who has these obligations, by contract or otherwise, the entity must select qualified investigators, provide those qualified investigators with sufficient data to conduct their investigation, ensure compliance with the investigational plan and protocols, maintain an effective plan and protocols, and promptly inform the FDA or investigators of new adverse events or newly discovered risks associated with the drug or device. In addition, the sponsor must maintain an open channel of communication between the participants, the investigators, and itself.

While much of the attention in the last few years has been focused upon the doctors, IRBs, and hospitals actually conducting the study and enrolling the patients, product sponsors can also be sued on a number of legal grounds. They can be sued for perpetrating a fraud on the FDA if there are allegations that the company was not forthcoming with all pertinent information during the process of obtaining FDA approval of the protocol or in obtaining the agency's approval of the individual drugs, devices, or biologics used in a clinical trial.

Sponsors can also be sued for having an allegedly defective product, either by errant manufacture or errant design. For instance, as was alleged in *In re St. Jude Medical Inc. Silzone Heart Valves Products Liability Litigation*, if an artificial heart valve was found to be prone to paravalvular leak, that device could be the basis of a design defect claim. Alternatively, plaintiffs can allege that a drug or device is defectively manufactured. For instance, if a vaccine intended to be a "killed vaccine" occasionally contained live viruses due to periodic problems in its manufacture, death or injuries from that product could serve as the basis of a "manufacturing defect" claim.

Aside from the risks associated with a product itself, companies can be sued for their corporate activity. If a company assured the public and those conducting a clinical trial that a particular drug could be given without a risk of stroke and this claim was inaccurate, then the company could be sued for breaching a warranty to participants.

In addition to making claims against a sponsoring company or others conducting a clinical trial based on disclosures to participants, plaintiffs also can sue for information that is withheld. Such failure-to-warn and intentional misrepresentation claims are common in products liability cases and were alleged in a Philadelphia clinical trials case, *Gukin v. Nagle*. In the *Gukin* case, plaintiffs claimed that the dangers associated with the medical device exceeded those expected by the average consumer. Typically, failure to warn claims are brought in addition to claims that sponsors violated state-enacted consumer protection laws designed to protect the public health and safety.

Other suits have been instituted against sponsors for discontinuing a clinical trial and failing to continue to supply an experimental treatment. In *Suthers v Amgen, Inc.*, a companion case to *Abney v Amgen, Inc.* (discussed below), the plaintiffs, who were participants in a Phase II clinical trial for Parkinson's disease, sued Amgen for discontinuing clinical trials for the treatment, despite the plaintiffs' protestations that the treatment was improving their health. Plaintiffs first sought a preliminary injunction to require Amgen to continue supplying

the treatment during the course of litigation. The court denied the motion for preliminary injunction, agreeing with Amgen that the plaintiffs could not establish a likelihood of success on their underlying claims. After additional briefing, the court dismissed all of plaintiffs' complaint for failure to state a claim. The court so held in large part because it found that Amgen had no contractual obligation to continue the treatment under the terms of the informed consent document, and that Amgen owed no duty to continue treatment to the plaintiffs under any theory of negligence or other breach of a duty. It is unclear at this writing whether the grant of this motion to dismiss will be appealed.<sup>1</sup>

### **Reference**

1. "Good Clinical Practice: A Question & Answer Reference Guide", Barnett International, 2006 pp.329-330

### **Source**

"Good Clinical Practice: A Question & Answer Reference Guide 2006," is available for \$39.95 at <http://www.barnettinternational.com/>