LEGAL CORNER

The Conflict of **Financial Interests in Clinical Trials**

by Susan W. Berson, J.D.

To advance scientific discovery and expedite the development of new treatments, many researchers accept funding from private industry (usually biotechnology and pharmaceutical). The drawback is that these "partnerships" create complex relationships involving researchers, private industry, and academic institutions. Some of these relationships have raised serious concerns about conflicts of interest and liability for errors, omissions, or adverse outcomes.

Over the last few years, a number of research studies failed to disclose investigators' and institutions' financial stakes, often in cases where the research has led to death or serious injury. The attention given in these high-profile cases has brought about a number of legislative, regulatory, and private-sector initiatives to address the issue of conflict of interest in clinical trials. Some in the industry even believe that disclosure alone is no longer an adequate safeguard for conflicts of interest in clinical trials.

In what many consider to be the "granddaddy" of cases relating to possible conflicts of interest in clinical trials, the California Supreme Court held that researchers did *not* have an obligation to disclose their significant monetary gain. In this case, the researchers had realized significant profit by creating and patenting a distinct cell line from a leukemia patient's spleen. (The spleen had been removed to slow the progress of the cancer.) The court made this ruling despite steps taken by the researchers to hide their research and commercial activities from the patient. The researchers even went so far as to require the patient to fly to California for several follow-up visits under the guise of treatment.

The court also ruled that the patient had no property interest in the cell line and no right to the significant monetary gain realized by the researchers. [See *Moore v. Regents of the University of California*, 79 3 P.2d 479 (Cal. 1990), cert. denied, 499 U.S. 936 (1991).] The court stated that the patient's interests had to be balanced with the need for innovative research and that the appropriate balance could be achieved by strengthening disclosure obligations. "So long as a physician discloses research and economic interests that may affect his judgment and the elimination of potential conflicts in certain instances, the patient is protected from conflicts of interest."

In another high-profile case, the family of a teenager who died as a result of participating in a clinical trial involving gene therapy sued the University of Pennsylvania. The case was at least partly based on the discovery that the trial's principal investigator had a significant ownership interest in the company whose drug was being tested and that the university also stood to benefit financially from the research, if the trial was successful. (On a separate note, the study had grossly underreported serious side effects from the trial.) Settled for an undisclosed sum, the case received great publicity because it highlighted the potential problems that exist when a researcher is motivated by more than the desire to advance science. (See, *Gelsinger v. University of Pennsylvania*.)

Although conflict of interest regulations currently mandate certain significant financial interests be disclosed under some circumstances, several initiatives being considered by the government and other organizations call for much stricter oversight of potential conflicts in clinical trials. These new guidelines aim to be more explicit about disclosure of financial interests and seek to identify scenarios where these interests may create potential conflicts in clinical trials. Congress has even tried to introduce legislation that would require financial interest disclosures and impose additional requirements on the institutional review boards that review clinical trials for, among other issues, financial interests. While the legislation has not advanced, further proposals are expected.

Most recently, two sets of guidelines have been published regarding financial conflicts of interest. One is by the Department of Health and Human Services and the other is by the American Society of Clinical Oncology (ASCO). Both guidelines focus on disclosure and review of financial interests, and the ASCO guidelines even recommend that certain financial interests and circumstances simply should not exist. While these policies go beyond the current requirements of disclosure of financial interests in research, they also establish a new standard for research that may be used in the future to assert liability for poor outcomes.

These initiatives demonstrate the attention being paid to the issue of clinical trials and conflict of interest. Maybe most importantly, these legislative and regulatory actions send a strong message that the need for innovative, cutting-edge research will not come at the cost of endangering the safety or the lives of the human volunteers participating in such studies.

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