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Heart of the Matter

Clinical Researcher as Entrepreneur

BY SIDNEY GOLDSTEIN, M.D.

In the past 25 years, there has been an explosion of investment by the pharmaceutical and medical-device industries in basic and applied medical research, from $2 billion in 1980 to $39 billion in 2004.

This support has had a profound influence on academia. It has changed the atmosphere in academic research from one of altruism to one with an entrepreneurial edge, as evidenced by the burgeoning numbers of invention disclosures and new patent applications from academic institutions. It has resulted in a significant increase in commercialization of academic medical centers and their faculties. It has also led to a natural desire for a greater ownership of concepts and profits by both the physician investigator and the sponsoring institution. In clinical trials, the boundary between the patient and the physician as an investigator and the physician as an inventor and entrepreneur has become more complex—particularly when they are the same person or the same institution.

There has been a recent spate of publicity about the financial relationships between physicians, academic research institutions, and companies developing new drugs and devices. Charges and countercharges have been made suggesting inappropriate involvement by physicians and medical institutions in devices or drugs that could result in significant financial return to them.

What is involved here is not obvious unethical behavior but the appearance that such behavior is taking place. It is not unusual that a clinical investigator would seek external high-risk financial support in order to carry an idea forward. The investigator who has invested in the research project would like to profit from that investment should the project become successful. Medical institutions, knowledgeable about new concepts, wish to invest in their development.

The patient who is asked to participate in a clinical trial knows nothing about the financial strings attached to the research project he or she is enrolled in. The patient is told there is a reasonable possibility, but no certainty, that the study could benefit them. The contract that the patient and physician sign, articulated in the consent form, indicates that scientific equipoise exists between active therapy and conventional therapy. The patient is motivated by the possibility of personally benefiting from the new therapy or at least the belief that it might benefit future patients. It is a contract founded on personal benefit and altruism. The injection of a profit motive by either the physician or the institution has the potential to contaminate the entire consent process.

The high road is one in which the inventor or institution has no patient contact in a research project from which either might profit financially. Physician scientists who wish to have their ideas tested should delegate the study and the analysis to more objective researchers. Likewise, institutions that have invested in the product should not participate in the investigation, to avoid the possibility of influencing staff participation in the trial and recruitment of patients. Anything short of this opens the investigator and institution to criticism of bias. ■

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