

Conflicts of Interest and the Public Trust

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University-based educators and researchers, as well as private practitioners, are in frequent contact with representatives from for-profit companies that provide "gifts" and financial support for teaching and research. The enticement begins very early in a physician's career: for my classmates and me, it started with black bags.

Dr Kassirer's colleague (1) is not alone in remembering which pharmaceutical company provided them. The timing of presenting the black bags early in our first year was wonderfully strategic, as was the inscription of our names on each. I must admit I was very happy to finally have a real symbol of the medical profession after so many hours of what seemed like year 5 of college. It took me a few days to come back to reality and store the bag in my closet. I'm not sure what happened to it, but I never carried it after that first day. On the other hand, at that time I did not have the courage to publicly state my unease with the unearned "gift."

Subsequently, offers came for "free" lunches, dinners, and tickets to various events followed by offers to serve as an "expert" with the usual lineup of speaking engagements and serving on advisory panels and boards, for an "honorarium" of course. **There should be little question about the expected effects of accepting free food, tickets, and even black bags. It has been shown that clinicians' decisions are affected by their interactions with pharmaceutical companies. (2)** This is no revelation; why else would anyone provide these "free" gifts except ultimately to assist in the selling of a product? The public is well aware of this problem, and it has become a favorite subject of recent newspaper articles.(3,4)

The issue of receiving reimbursement for providing time and expertise, as a speaker (teacher), advisor, or researcher, is more complex. Persons asked to provide expertise as teachers or researchers generally are selected from a pool of those best prepared and experienced in the field. Who is better equipped to teach or perform the studies, and why shouldn't they be rewarded for their work? The problem lies in the conflict of interest that results from these relationships. It is vitally important to understand that a conflict of

interest does not necessarily result in an outcome different than the result would have been without such conflict. The potential for differing results is the problem at hand.

Balance must be maintained between the need for research projects to be reasonably funded and performed by the best possible investigators and the relative paucity of public funds for clinical research. In 1999, the National Institutes of Health (NIH) provided \$17.8 billion for research, and the major proportion was expended for basic research; the top 10 pharmaceutical companies spent \$22.7 billion, primarily on clinical research (Hamilton Moses III, MD, The Boston Consulting Group, personal communication, 2000). The likelihood that a clinical investigator would be funded by private vs public funds is substantial. Furthermore, a recent study by USA Today revealed that **more than half of the advisors** to the Food and Drug Administration (FDA) have financial relationships with pharmaceutical companies that have an interest in FDA decisions. (5)

When an investigator has a financial interest in or funding by a company with activities related to his or her research, the research is:

- **lower in quality (6,7)**
- **more likely to favor the sponsor's product (8-11)**
- **less likely to be published (12,13)**
- **more likely to have delayed publication (14)**

Institutional safeguards can substantially mitigate the negative effects of funding from companies with a vested interest in the results.

Boyd and Bero (15) provide a case study of the University of California, San Francisco faculty's financial relationships with industry. By 1999, 225 researchers (almost 8% of total faculty investigators) had been involved in 488 disclosures. One can only postulate the results from other institutions that accept private funding for research, and it is an unusual institution that does not do so. Therefore, all research universities should emulate Boyd and Bero's study to determine the extent of their faculty members' involvement with industry and to institute proper oversight.

Cho et al (16) report on the content of conflict of interest policies at 89 biomedical research institutions receiving the most NIH funding in 1998. Their results show that while there appears to be a lack of

specificity about the exact nature of the relationships of their faculties with industry, the vast majority (89%) at least had mechanisms for disclosure to the institution. However, **only 19% had specific prohibitions or limitations of activities related to research or teaching, and 38% had institutional committees to review conflicts of interest.** As the amount and proportion of funding from private corporations for research increase, it is vital that all institutions that accept these funds develop methods for disclosure and oversight.

In a Commentary, Korn (17) addresses the complexities of ensuring that academic medical centers preserve the confidence and support of the public and government agencies while maintaining the funding necessary to remain on the cutting edge of research. He discusses how the inevitable conflict of interest issues must be managed by academic centers.

Finally, Kahn and colleagues (18) illustrate what can happen when disagreement occurs between the funding sponsor and the investigators when the sponsor has a proprietary interest in the findings. **The investigators report that some data were not made available to them by the sponsor.** The integrity of the research process rests on a sound study design and the disclosure of all pertinent results, whether positive or negative, based on analysis of all necessary data.

In this case the data set is incomplete, but the investigators, peer reviewers, and editors believe it to be of sufficient merit to warrant the conclusions. Our decision to publish this study is based on the belief that the integrity of the research process must be protected and preserved. The authors have provided the best research possible under the circumstances. If further data are or become available that refute or alter the conclusion of this study, I welcome submission of such material. Science is a dynamic and ongoing process, and we must allow it to continue.

Unlike the majority of, if not all, for-profit businesses in our capitalistic society, managed health care corporations have not provided funding for research and development (education). This is true despite the advantages they derive from the research and education provided primarily by academic medical centers. Furthermore, there is little chance that sufficient funding for important clinical research, especially expensive clinical trials, will be forthcoming from sources other than

sponsors with a vested interest in the results. Those best prepared and experienced to carry out such complex studies generally are faculty in academic institutions. Therefore, **it is vitally important that these institutions develop conflict of interest policies, have oversight mechanisms in place, and continuously monitor the relationships of faculty with sponsoring companies and agencies.**

Without these policies and procedures, the academic institutions where most clinical research is based and their faculty members who perform the research are in grave danger of losing the support and respect of the public. Without this support and respect, trust in new medical discoveries and their applications will not be forthcoming. **Without trust, medical research is doomed.**

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