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Conflict-of-interest management: Efforts and insights from the Association of American Medical Colleges

ABSTRACT

The Association of American Medical Colleges has issued three major reports to help academic medical centers manage financial conflicts of interest in clinical research. One report addresses individual conflicts, another addresses institutional conflicts, and the third is a survey-based assessment of institutions' performance to date in conflict-of-interest management. While implementation of policies to manage individual conflicts has been significant and widespread, the extent to which institutional conflicts are being managed is unclear. Developing effective and accepted policies to manage potential conflicts involving the funding of education remains a major challenge.

The Association of American Medical Colleges (AAMC) is the representative organization of academic medicine. It comprises all 125 US and 17 Canadian accredited medical schools and nearly 400 major teaching hospitals and health systems. Through these institutional members, the AAMC represents 109,000 faculty members, 67,000 medical students, and 104,000 resident physicians.

With diverse interests at work, the AAMC's mission is to try to find consensus, especially on vexing issues such as conflict of interest. In fact, one of our newest affiliated entities, called the Forum on Conflict of Interest in Academe, is devoted exclusively to this topic. This article briefly reviews AAMC efforts to help its members manage potential conflicts of interest in clinical research, and concludes by assessing progress to date.

Dr. Kirch reported that he has no financial interests, relationships, or affiliations that pose a potential conflict of interest with this article.

A QUARTER CENTURY OF CHANGE HAS LED TO COMPLEXITY AND CONFLICTS

When I completed my residency training in the early 1980s, I remember firmly believing that the Hippocratic oath's guidance of "above all, do no harm" created a shield of self-regulation that would protect me in all situations. I had no idea just how complicated our world would become in terms of the ethical questions that have come to be intertwined with much of medical progress since then.

Megatrends at work

A number of megatrends have driven these complex interactions:

Complexity of science. The rapidly expanding complexity of biomedical science over the past quarter century is well established and does not require further discussion for this audience.

"Privatization" of higher education. Our great public universities—even those institutions forged 150 years ago in the land-grant tradition of access to higher education for all—have been forced to rely less on public funds and more on private sources of support.

Expectations for economic growth. A corollary to privatization, and one that applies to both public and private institutions, is the growing expectation that academic medical centers have to be the economic engines of our communities. In many major US cities, the largest employer today is the academic health center.

Pivotal role of Bayh-Dole

These trends, together with the Bayh-Dole Act of 1980, have largely brought us where we are today. The Bayh-Dole Act, which gave US universities intellectual property control of their inventions that arose from federal government-funded research, created a wave of entrepreneurship within academic medicine. Shortly thereafter, however, problems with potential conflicts of interest began to emerge.

TABLE 1
Association of American Medical Colleges reports on financial conflicts of interest in clinical research*

Title: *Protecting Subjects, Preserving Trust, Promoting Progress: Policy and Guidelines for the Oversight of Individual Financial Interests in Human Subjects Research*
Issued: December 2001
At a glance: Provides guidance on *individual* financial interests in human subjects research

Title: *Protecting Subjects, Preserving Trust, Promoting Progress II: Principles and Recommendations for Oversight of an Institution's Financial Interests in Human Subjects Research*
Issued: October 2002
At a glance: Offers a conceptual framework for assessing *institutional* conflicts of interest and specific recommendations for oversight of certain financial interests in human subjects research

Title: *U.S. Medical School Policies on Individual Financial Conflicts of Interest: Results of an AAMC Survey*
Issued: September 2004
At a glance: Reports findings of an AAMC survey on conflict-of-interest management trends

* Full reports available at www.aamc.org/research/coi/

AAMC EFFORTS TO GUIDE CONFLICT-OF-INTEREST MANAGEMENT

As we have heard earlier today, there is a spectrum of philosophies on how to address conflicts of interest in medicine. At one end is the proposal to prohibit all relationships between academia and industry, which many fear would stifle innovation. At the other end is the admonition to allow relationships to grow unfettered, which others fear would undermine public trust and credibility. The middle ground consists of efforts to *manage* these complex relationships, which is where the AAMC's efforts have been focused.

As early as 1990, the AAMC began to publish guidelines to address faculty "conflicts of commitment" as well as conflicts of interest. In 1995, significant federal regulations were enacted regarding financial conflicts of interest in projects funded by the US Public Health Service, including grants from the National Institutes of Health. These federal regulations further heightened interest in conflict of interest as an issue, and in recent years the AAMC has issued three major reports on financial conflicts of interest in clinical research **(Table 1)** that have served as landmarks for the academic medical community.

First report: Guidance for individual conflicts

The first report was issued in December 2001 by an AAMC task force led by William Danforth, chancellor emeritus of Washington University of St. Louis. It was prompted by a speech by my predecessor as AAMC president, Jordan Cohen, at the AAMC's annual meeting in 2000. The speech, entitled "Trust Us to Make a Difference," was an eloquent plea to recapture the public's trust.

This first report, which is specific to individual conflicts of interest, exemplifies the shift that had taken place in the vocabulary surrounding these issues, as it contains several pages of definitions and serves as a road map for those of us struggling with these matters. It also describes how to construct monitoring efforts and, in my view, has become a useful document for many of our institutions. As confirmation of the controversy that surrounds conflict-of-interest policies, one member of the 28-member task force declined to endorse the report, primarily out of a concern that its recommendations would be an impediment to research innovation.

Second report: Guidance for institutional conflicts

The second report, issued in October 2002, is a continuation of the themes promulgated in the first report. It focuses, however, on institutional conflicts of interest, emphasizing the need for academic institutions to put a firewall between the management of their own financial interests, including those deriving from technology transfer, and the protection of human subjects. It also provides guidance on the process of evaluating institutional financial interests.

Third report: Survey of performance

The third report, issued in September 2004, presents results of a survey by the AAMC to assess US medical schools' performance in managing conflicts. Although this report found high levels of acceptance of AAMC recommendations regarding rigorous standards for conflict-of-interest management, some concerns were cited. These included a low rate of evaluation of significant financial interests by standing committees (prior to final review by the institutional review board) and a lack of public representatives in conflict-of-interest discussions.

Latest initiatives

A subsequent report, *Principles for Protecting Integrity in the Conduct and Reporting of Clinical Trials*, was based on the proceedings of an invitational conference convened by the AAMC in June 2005. It features standards to guide institutions and their investigators in

the analysis and reporting of clinical trials in which they participate.

Looking ahead, Roy Vagelos, the former CEO of Merck & Co. and a participant in today's conference, has graciously agreed to chair a new AAMC task force that will convene in the next few months in an effort to develop guiding principles for industry support of medical education.

AAMC conflict-of-interest efforts are highlighted at www.aamc.org/research/coi/, which is a popular Web page on our site. Access to all of the aforementioned documents is granted on this page.

HOW HAVE WE DONE SO FAR?

I will conclude with a brief personal perspective on how well the US academic medical community has addressed conflict-of-interest management to date in several different areas.

Individual conflicts

I am impressed by the progress we have made in handling individual conflicts of interest. I believe that the rules have become clearer, and I see fewer and fewer failures to appropriately disclose and manage potential individual conflicts. I give the general community high marks in this regard.

Institutional conflicts

I am not certain where we stand in terms of institutional conflicts. An AAMC survey is currently in progress to gauge the types of systems that are (or should be) in place to manage institutional conflicts.

Conflicts involving support of education

The most difficult area to address, I believe, involves potential conflicts surrounding the support of medical education. As we heard earlier in this conference, this area involves many oblique issues, and speculation about motives, behavior, and influence abounds. The AAMC task force that will soon convene hopefully will add clarity regarding this most challenging topic.

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