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The rapidly changing landscape of biomedical conflicts of interest

Academic medical centers (AMCs) have undergone major changes in the way they relate to the biopharmaceutical and medical device industries. This has led to changes in the public's view of AMCs with respect to these relationships—a view that is often refracted through the lenses of ambitious investigative reporters. The academic medical community must construct its relationships with industry in ways that merit the public's trust.

A shared desire to discuss and understand these changes prompted a gathering of some of the nation's most prominent thought leaders on biomedical conflicts of interest at Cleveland Clinic on September 20, 2006. The resulting event, "A National Dialogue on Biomedical Conflicts of Interest and Innovation Management," featured a number of perspectives on these issues from a slate of speakers hailing from AMC faculties, industry, government regulatory and prosecutorial offices, the bioethics community, and the media. This journal supplement is a collection of edited transcripts from that conference, with the essence of the messages from the presenters and audience members faithfully preserved.

FACTORS BEHIND THE CHANGES AT AMCs

The changes in AMC-industry ties have been precipitated by a number of factors:

- The Bayh-Dole Act and other federal and state initiatives encouraging commercialization of discoveries from academic laboratories
- A shift from performing science solely to advance the state of knowledge to keeping one eye on which discoveries emanating from AMC labs might become practical advances to improve patient care
- The deluge of discoveries resulting from the cracking of the genetic code
- Federal research funding levels that fall short of feeding the nation's biomedical science appetite
- A growing biotechnology industry that is hungry for academic partnerships and has fine-tuned the art of forming new companies.

Whatever the principal driving forces, these changes at AMCs have manifested themselves in increased entrepreneurial activity and an expanded infrastructure for technology transfer.

NOVEL AND COMPLEX PREDICAMENTS

The growth and variety of academic-industry partnerships has resulted in novel and complex predicaments, in which financial gains appear as though they could compromise the validity of scientific data or the treatment of patients. Some of these predicaments stem from gifts or unrestricted grants from grateful industry partners, or from medical product marketers trying to influence buying or prescribing habits. Some arise from consulting relationships, and others from licensing arrangements. Still others stem from spin-off companies, in which employees of academic institutions, or the institutions themselves, stand to gain from the future success of commercialized discoveries or inventions.

Are all of these arrangements evil? Can they be allowed to go on in such a way that the inherent conflicts of interest are avoided? Can they proceed, sufficiently protected from bias, through artful and conscientious "management" of their inherent conflicts, when avoiding these conflicts would be tantamount to killing a beneficial project? These questions do not have easy answers, although some people believe there are certain "conflicted" arrangements that provide no room for management and should be forbidden outright.

Differing views of gifts and grants

Many believe that all gifts to physicians and on-campus marketing by industry should be banned, and steps related to this have recently been taken by a handful of AMCs, including those of Stanford

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University, Yale University, and the University of Pennsylvania. Others will surely follow. The Pew Charitable Trusts is funding a $6 million "Prescription Project" to document the effects of such gifts on prescribing practices and to advocate restrictions on physicians' acceptance of gifts. However, the industry gifts in the form of grants that fund fellowships and educational conferences are likely to continue to be handled in varying ways by different AMCs.

Consulting for industry: To ban or to manage?

Consulting relationships are viewed differently. When industry wants a consultant to help it develop a new product or understand the medical implications of a product, it looks to academia. Specifically, it often looks to clinical scientists whose clinical insights are known to be superlative, who are thought leaders in their field, whose research is at the forefront, and who are respected by their peers. When AMCs recruit faculty, they look for people with these exact same attributes. Is it surprising, then, that the faculties of AMCs do a lot of consulting for industry?

For this reason, there is a strong tendency to try to manage the conflicts created by consulting for industry rather than ban the consulting itself. Few are suggesting that investigators outside of the National Institutes of Health (NIH) be subject to limitations on consulting as strict as those for intramural NIH researchers, which generally prohibit any consulting for companies that develop biomedical products (see pages S29–S31 for details).

When to hand off commercialized discoveries to disinterested parties?

What about the conflicts that directly arise from the commercialization of discoveries made at AMCs? In many cases there is arguably an early stage to the development of a discovery, during which the knowledge base, insights, laboratory resources, and "fire in the belly" of the discoverer/inventor are essential to bring the discovery to a level at which further development and validation can be turned over to an uninvolved party. Currently AMCs vary significantly in how they handle the conflicts that arise from keeping the "conflicted" discoverer/inventor involved in these early studies. Approaches range from banning the discoverer/inventor from performing research under certain circumstances to trying to manage all of the potential conflicts with adequate firewalls between the financial inducements on one side and the data and patient care on the other.

These approaches will continue to evolve. Only within the last few years have AMCs developed formalized and specific *institutional* conflict-of-interest policies to guide their faculty members and corporate leaders when the institution, or one of its officials, is a part owner or licensee of a discovery and related research on that discovery continues at the AMC.

SHIFTING LANDSCAPE GIVES RISE TO A DIVERSITY OF VIEWPOINTS

A confluence of competing interests

At a basic level, the challenge we face arises from a confluence of competing desires, needs, and duties:

- The desire of AMCs to bring forth new discoveries to benefit patients
- The need for AMCs to find new sources of income as their reimbursements dwindle and their research programs outpace the growth of federal funding
- The need for AMCs' industry partners to make money for their shareholders
- The duty of government to protect patients and data from the effects of bias that would favor profit at the expense of best clinical practices or data integrity.

All of us need to reexamine what we do to accommodate the changing milieu brought about by these competing interests. This supplement serves as a good starting point by providing readers with a clear sense of the variability of stances on the above issues and a striking picture of the dramatically changing landscape.

A sampling of perspectives

Dr. Philip Pizzo, dean of Stanford's School of Medicine, describes recent steps to ban industry marketing and industry gifts to physicians at all Stanford facilities (pages S10–S11). Dr. Edward Miller, dean of Johns Hopkins School of Medicine and CEO of Johns Hopkins Medicine, details ongoing efforts at his institution to formulate and implement an institutional conflict-of-interest policy (pages S70–S72).

The consequences of noncompliance with current standards are put into sobering perspective by Associate US Attorney James Sheehan (pages S63–S67).

The considerable efforts being made by industry to ensure ethical behavior in its partnerships with AMCs are touched on in numerous articles (see pages S12–S13, S26–S28, S38–S44, S45–S48).

Challenges to potentially overzealous limitations on these partnerships are offered by Dr. Thomas Stossel of Harvard Medical School, who views many such limitations as being based on shaky data and/or detrimental to medical progress (pages S14–S15).

The Association of American Medical Colleges (AAMC) has been one of the most influential forces driving AMCs toward more rigorous, transparent, and

uniform conflict-of-interest policies and procedures. Dr. Darrell Kirch, the new president of the AAMC, describes these past efforts as well as new AAMC initiatives to push institutions further (pages S23–S25).

This is but a sampling of the wealth of thought and information in this supplement; I remind readers that some of the supplement's most engaging reading is in the five interactive panel discussions.

In fact, the high degree of interchange of ideas was one of the clear successes of this "National Dialogue on Biomedical Conflicts of Interest and Innovation Management." Panel moderators made certain that the holders of disparate points of view had to face one another's ideas. Speakers and panelists were further probed by the conference's particularly interactive audience.

This audience of more than 300 was made up of representatives of the same diversity of communities as the speakers—biomedical research facilities, industry, government, the bioethics community, medical societies, the legal community, and the media. More than one third of attendees were front-line "practitioners" in these issues—faculty and administrators at AMCs who deal with biomedical conflicts of interest on a day-to-day basis. This latter group of attendees represented 40 of the nation's 125 medical schools and came from as far afield as Washington, Oregon, California, New Mexico, Texas, Louisiana, Alabama, and Florida, as well as from states closer by.

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