CONFLICT OF INTEREST IN MEDICAL RESEARCH, EDUCATION, AND PRACTICE

Statement of

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before the

Special Committee on Aging
United States Senate

July 29, 2009

Good afternoon, Mr. Chairman and members of the Committee. Thank you for the opportunity to speak to you today. My name is Eric Campbell, Associate Professor at the Institute for Health Policy and the Department of Medicine at Massachusetts General Hospital and Harvard Medical School. Recently, I served as a member of the Institute of Medicine (IOM) committee that produced the report, *Conflict of Interest in Medical Research, Education, and Practice*. Established in 1970 under the charter of the National Academy of Sciences, the IOM provides independent, objective, evidence-based advice to policymakers, health professionals, the private sector, and the public.

The committee was convened by the IOM to examine conflict of interest in medicine and to develop recommendations to identify, limit, and manage such conflicts without affecting constructive collaborations with industry. The committee held six meetings between November 2007 and October 2008, four of which included public sessions. The committee received oral and written statements from stakeholders such as academic leaders, biomedical researchers, professional societies, consumer groups, accreditors, and federal agencies. The committee also reviewed relevant literature and commissioned two papers to inform their analyses and recommendations.

The study focused on financial conflicts involving pharmaceutical, medical device, and biotechnology companies. The committee's final report, which includes 16 recommendations, describes an important goal of conflict of interest policies: to prevent bias rather than try to remedy the harm caused by compromised judgments in research, education, or practice. The study was sponsored by the National Institutes of Health, Robert Wood Johnson Foundation, Greenwall Foundation, ABIM Foundation, Burroughs Wellcome Fund, and Josiah Macy Jr. Foundation.

Society relies upon research to advance scientific discoveries and develop new medications and medical devices to benefit both individuals and public health. Research partnerships among industry, academia, and government are essential to the discovery process. In recent decades, corporate funding for research has expanded substantially; industry now funds more than half of all biomedical research in the United States.

Although patients and the public benefit from constructive collaborations between academic medicine and industry, particularly in moving discoveries from basic science into improved patient care, financial ties between medicine and industry can create significant risks that these relationships will inappropriately influence doctors' judgments and actions. Conflicts of interest jeopardize the integrity of scientific research and also threaten the objectivity of medical professionals' education, affect the quality of patient care, and erode the public's confidence in medicine. The IOM report spells out a reasonable strategy to protect against financial conflicts while at the same time allowing productive relationships between the medical community and industry.

DISCLOSURE

Lack of disclosure of financial relationships is a problem that has been highlighted in several media reports about physicians' and researchers' conflicts of interest. To support research institutions, professional societies, medical journals, and others who rely on

disclosures by individuals and institutions, the report calls on Congress to create a national public reporting program for the industry. This program should require pharmaceutical, medical device, and biotechnology companies to report, through a public Web site, payments they make to physicians, researchers, health care institutions, professional societies, patient advocacy and disease-specific groups, and providers of continuing medical education. A public record like this could serve as a deterrent to inappropriate relationships and undue industry influence. It also would provide medical institutions with a way to verify the accuracy of information that physicians, researchers, and senior officials have disclosed to them. The report also calls for the development of standardized categories for disclosure of relationships with industry.

INSTITUTIONAL CONFLICTS OF INTEREST

In medical research, conflicts may exist at both the institutional and the individual level. Thus, conflict of interest policies must address both. Institutional conflicts typically arise when research conducted within an institution could affect an investment holding by an institution or a patent the institution licenses to a company. Conflicts can also be caused by the financial relationships senior institutional officials have with industry.

The Public Health Service (PHS) requires institutions that receive PHS research grants to adopt policies on individual conflict of interest. The report suggests that the National Institutes of Health (NIH) continue its recent efforts to provide guidance to grantee institutions and to make public information about research institutions whose policies are not in full compliance with PHS regulations. The report also recommends that governing boards of medical institutions establish standing committees to oversee conflicts of interest at the institutional level and that NIH require its research grantees to adopt such policies.

CLINICAL RESEARCH

It is critical for public trust that research institutions protect the integrity of the medical research that is the foundation of clinical practice and education. Bias in the design and conduct of clinical trials may expose research participants to risks without the prospect that the trials will generate valid, generalizable knowledge. Moreover, such bias and also bias in the reporting of research may result in compromised findings being submitted to the Food and Drug Administration for approval of drugs or devices. Further, it may also expose much larger numbers of patients to ineffective or unsafe clinical care.

The committee recommends, as described in Recommendation 4.1 of the report, that, in general, researchers with a significant conflict of interest not participate in research with human participants. For example, if a researcher holds the patent on an intervention being tested in a trial, she generally should not conduct the study. Exceptions may be made if an investigator's participation is vital to the safe and rigorous conduct of research and if mechanisms are in place to manage the conflict, safeguard research participants, and protect the integrity of the research. This recommendation is similar to the AAMC "rebuttable presumption" described earlier in this chapter.

RECOMMENDATION 4.1 of the IOM's report, *Conflict of Interest in Medical Research, Education, and Practice*, reads, **"Academic medical centers and other research institutions should establish a policy that individuals generally may not conduct research with human participants if they have a significant financial interest in an existing or potential product or a company that could be affected by the outcome of the research. Exceptions to the policy should be made public and should be permitted only if the conflict of interest committee (a) determines that an individual's participation is essential for the conduct of the research and (b) establishes an effective mechanism for managing the conflict and protecting the integrity of the research."**

Compared to clinical research, conflicts of interest involving nonclinical research have received much less attention. The IOM committee found differing opinions of the risk involved when nonclinical investigators have a financial stake in the outcome of a research project. This area warrants further discussion and investigation, and the committee suggests that the NIH play a role in promoting and organizing this discussion. At a minimum, research institutions should evaluate individual and institutional financial relationships in nonclinical research to assess the risk they pose to scientific judgment and then respond as appropriate to protect the integrity of the research.

CONTINUING MEDICAL EDUCATION

Physicians commit to lifelong learning to keep pace with new knowledge and skills and to maintain their current skills. Most state licensing boards, specialty boards, and hospitals require accredited continuing medical education for relicensure, recertification, or staff privileges.

According to the Accreditation Council for Continuing Medical Education, about half of all funding for accredited continuing medical education programs now comes from commercial sources; the proportion is even higher for some categories of providers. The fees paid by program attendees once provided the majority of provider income, but today industry-supported programs are often provided free or at reduced cost to physicians. This substantial industry support indirectly subsidizes physicians who pay less for many programs than they otherwise would.

The members of the IOM committee generally agreed that accredited continuing medical education has become far too reliant on industry funding and that such support tends to promote a narrow focus on medical products and a neglect of broader education on alternative strategies for preventing and managing health conditions and other important issues, such as communication with patients. Given the lack of validated and efficient tools for preventing or detecting bias in educational presentations and programs, industry funding creates a substantial risk of bias as education providers seek to maintain or attract industry support for future programs.

Although the committee did not reach agreement on a specific path to reform of continuing medical education, it concluded that the current system of funding is unacceptable and should not continue. As noted in Recommendation 5.3, the report calls

on representatives from key groups—education providers, certification boards, accreditation organizations, and the public among others—to convene a consensus process to develop a new system of funding for accredited continuing medical education that is free of industry influence, provides high-quality education, and enhances public trust.

RECOMMENDATION 5.3 of the IOM's report, *Conflict of Interest in Medical Research, Education, and Practice*, states, **"A new system of funding accredited continuing medical education should be developed that is free of industry influence, enhances public trust in the integrity of the system, and provides high-quality education. A consensus development process that includes representatives of the member organizations that created the accrediting body for continuing medical education, members of the public, and representatives of organizations such as certification boards that rely on continuing medical education should be convened to propose within 24 months of the publication of this report a funding system that will meet these goals."**

In general, the committee believed that such a consensus process was likely to result in a funding system that was feasible and that did not create unnecessary administrative burdens or have unintended adverse consequences. The committee left open the possibility that industry funding might be determined to be acceptable under certain circumstance and with appropriate safeguards.

CONCLUSION

Society traditionally has placed great trust in physicians and researchers, granting them the considerable leeway to regulate themselves. However, lawmakers and others are increasingly asking whether conflicts of interest in medicine require stronger measures. Taken together, the changes recommended in this report should reduce the risk that financial ties with industry will unduly influence the judgments of researchers and research institutions. The changes should not burden socially valuable collaborations between industry and academic researchers and research institutions. Rather, they should help justify and maintain public trust in the integrity of these collaborations.

Thank you for the opportunity to testify. I would be happy to address any questions the Committee might have.

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BIOGRAPHICAL SKETCH

Eric G. Campbell, Ph.D., is an Associate Professor at the Institute for Health Policy (IHP) and the Department of Medicine at Massachusetts General Hospital and Harvard Medical School. His main research interests lie in understanding the effects of academic-industry relationships on the process and outcomes of biomedical research, investigating the effects of local health care market competition on the activities and attitudes of medical school faculty and understanding the impact of data-sharing and withholding on academic science. In addition, he is researching the role of organizational culture in

promoting patient safety and he is participating in a national evaluation of the use of health information technology for the Office of the National Coordinator of Health Information Technology. Dr. Campbell has published numerous articles in professional journals and has delivered numerous presentations at local, national and international conferences on health care policy, medical education and science policy. He served on the IOM Committee on Alternative Funding Strategies for DOD's Biomedical Research Program and the IOM Committee on Conflict of Interest in Medical Research, Education, and Practice.