

**Institute of Medicine Conflict of Interest in Medical Research, Education and Practice
Full Recommendations 4-28-09**

RECOMMENDATION 3.1 Institutions that carry out medical research, medical education, clinical care, or practice guideline development should adopt, implement, and make public conflict of interest policies for individuals that are consistent with the other recommendations in this report.

To manage identified conflicts of interest and monitor the implementation of management recommendations, institutions should create a conflict of interest committee.

That committee should use a full range of management tools, as appropriate, including elimination of the conflicting financial interest, prohibition or restriction of involvement of the individual with a conflict of interest in the activity related to the conflict, and providing additional disclosures of the conflict of interest.

RECOMMENDATION 3.2 As part of their conflict of interest policies, institutions should require individuals covered by their policies, including senior institutional officials, to disclose financial relationships with pharmaceutical, medical device, and biotechnology companies to the institution on an annual basis and when an individual's situation changes significantly. The policies should:

- Request disclosures that are sufficiently specific and comprehensive (with no minimum dollar threshold) to allow others to assess the severity of the conflicts;
- Avoid unnecessary administrative burdens on individuals making disclosures; and
- Require further disclosure, as appropriate, for example, to the conflict of interest committee, the institutional review board, and the contracts and grants office.

RECOMMENDATION 3.3 National organizations that represent academic medical centers, other health care providers, and physicians and researchers should convene a broad-based consensus development process to establish a standard content, a standard format, and standard procedures for the disclosure of financial relationships with industry.

RECOMMENDATION 3.4 The U.S. Congress should create a national program that requires pharmaceutical, medical device, and biotechnology companies and their foundations to publicly report payments to physicians and other prescribers, biomedical researchers, health care institutions, professional societies, patient advocacy and disease-specific groups, providers of continuing medical education, and foundations created by any of these entities. Until the Congress acts, companies should voluntarily adopt such reporting.

RECOMMENDATION 4.1 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.

RECOMMENDATION 5.1 For all faculty, students, residents, and fellows and for all associated training sites, academic medical centers and teaching hospitals should adopt and implement policies that prohibit:

- The acceptance of items of material value from pharmaceutical, medical device, and biotechnology companies, except in specified situations;
- Educational presentations or scientific publications that are controlled by industry or that contain substantial portions written by someone who is not identified as an author or who is not properly acknowledged;
- Consulting arrangements that are not based on written contracts for expert services to be paid for at fair market value;
- access by drug and medical device sales representatives, except by faculty invitation, in accordance with institutional policies, in certain specified situations for training, patient safety, or the evaluation of medical devices; and
- The use of drug samples, except in specified situations for patients who lack financial access to medications.

Until their institutions adopt these recommendations, faculty and trainees at academic medical centers and teaching hospitals should voluntarily adopt them as standards for their own conduct.

RECOMMENDATION 5.2 Academic medical centers and teaching hospitals should educate faculty, medical students, and residents on how to avoid or manage conflicts of interest and relationships with pharmaceutical and medical device industry representatives. Accrediting organizations should develop standards that require formal education on these topics.

RECOMMENDATION 5.3 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.

RECOMMENDATION 6.1 Physicians, wherever their site of clinical practice, should:

- Not accept of items of material value from pharmaceutical, medical device, and biotechnology companies except when a transaction involves payment at fair market value for a legitimate service;
- Not make educational presentations or publish scientific articles that are controlled by industry or contain substantial portions written by someone who is not identified as an author or who is not properly acknowledged;
- Not enter into consulting arrangements unless they based on written contracts for expert services to be paid for at fair market value;
- Not meet with pharmaceutical and medical device sales representatives except by documented appointment and at the physician's express invitation; and
- Not accept drug samples except in certain situations for patients who lack financial access to medications.

Professional societies should amend their policies and codes of professional conduct to support these recommendations.

Health care providers should establish policies for their employees and medical staff that are consistent with these recommendations.

RECOMMENDATION 6.2 Pharmaceutical, medical device, and biotechnology companies and their company foundations should have policies and practices against:

- Providing physicians with gifts, meals, drug samples (except for use by patients who lack financial access to medications), or other similar items of material value and against asking physicians to be authors of ghostwritten materials.
- Consulting arrangements should be for necessary services, documented in written contracts, and paid for at fair market value.
- Companies should not involve physicians and patients in marketing projects that are presented as clinical research.

RECOMMENDATION 7.1 Groups that develop clinical practice guidelines should generally exclude as panel members individuals with conflicts of interest and should not accept direct funding for clinical practice guideline development from medical product companies or company foundations.

Groups should publicly disclose with each guideline their conflict of interest policies and procedures and the sources and amounts of indirect or direct funding received for development of the guideline.

In the exceptional situation in which avoidance of panel members with conflicts of interest is impossible because of the critical need for their expertise, then groups should:

- Publicly document that they made a good-faith effort to find experts without conflicts of interest by issuing a public call for members and other recruitment measures;
- Appoint a chair without a conflict of interest;
- Limit members with conflicting interests to a distinct minority of the panel;
- Exclude individuals who have a fiduciary or promotional relationship with a company that makes a product that may be affected by the guidelines;
- Exclude panel members with conflicts from deliberating, drafting, or voting on specific recommendations; and
- Publicly disclose the relevant conflicts of interest of panel members.

RECOMMENDATION 7.2 Accrediting and certification bodies, health insurers, public agencies, and other similar organizations should encourage institutions that develop clinical practice guidelines to adopt conflict of interest policies consistent with the recommendations in this report. Three desirable steps are for:

Journals to require that all clinical practice guidelines accepted for publication describe (or provide an Internet link to) the developer's conflict of interest policies, the sources and amounts of funding for the guideline, and the relevant financial interests of guideline panel members, if any;

The National Guidelines Clearinghouse to require that all clinical practice guidelines accepted for posting describe (or provide an Internet link to) the developer's conflict of interest policies, the sources and amounts of funding for development of the guideline, and the relevant financial interests of guideline panel members, if any; and accrediting and certification organizations, public and private health plans, and similar groups to avoid using clinical practice guidelines for performance measures, coverage decisions, and similar purposes if the guideline developers do not follow the practices recommended in this report.

RECOMMENDATION 8.1 The boards of trustees or the equivalent governing bodies of institutions engaged in medical research, medical education, patient care, or practice guideline development should establish their own standing committees on institutional conflicts of interest.

These standing committees should:

- Have no members who themselves have conflicts of interest relevant to the activities of the institution;

- Include at least one member who is not a member of the board or an employee or officer of the institution and who has some relevant expertise; create, as needed, administrative arrangements for the day-to-day oversight and management of institutional conflicts of interest, including those involving senior officials;
- Submit an annual report to the full board, which should be made public but in which the necessary modifications have been made to protect confidential information.

RECOMMENDATION 8.2 The National Institutes of Health should develop rules governing institutional conflicts of interest for research institutions covered by current U.S. Public Health Service regulations. The rules should require the reporting of identified institutional conflicts of interest and the steps that have been taken to eliminate or manage such conflicts.

RECOMMENDATION 9.1 Accreditation and certification bodies, private health insurers, government agencies, and similar organizations should develop incentives to promote the adoption and effective implementation of conflict of interest policies by institutions engaged in medical research, medical education, clinical care, or practice guideline development. In developing the incentives, these organizations should involve the individuals and the institutions that would be affected.

RECOMMENDATION 9.2 To strengthen the evidence base for the design and application of conflict of interest policies, the U.S. Department of Health and Human Services should coordinate the development and funding of a research agenda to study the impact of conflicts of interest on the quality of medical research, education, and practice and on practice guideline development and to examine the positive and negative effects of conflict of interest policies on these outcomes.