INSTITUTE OF MEDICINE

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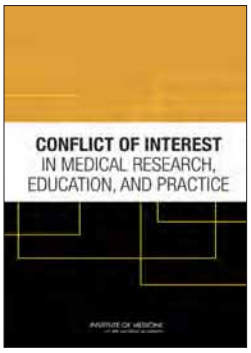
Conflict of Interest in Medical Research, Education, and Practice



Collaborations between physicians or medical researchers and pharmaceutical, medical device, and biotechnology companies can benefit society—most notably by promoting the discovery and development of new medications and medical devices that improve individual and public health. However, financial ties between medicine and industry may create conflicts of interest. Such conflicts present the risk of undue influence on professional judgments and thereby may jeopardize the integrity of scientific investigations, the objectivity of medical education, the quality of patient care, and the public's trust in medicine.

Recent news stories have documented troubling interactions between industry and physicians, researchers, and medical institutions. These situations, which could undermine public confidence in medicine, may include

- companies and academic investigators not publishing negative results from industry-sponsored clinical trials or delaying publication after trial completion;
- physicians and researchers failing to disclose substantial payments from pharmaceutical companies as required by universities, research sponsors, or medical journals; and
- settlements between federal prosecutors and medical device and pharmaceutical companies related to alleged illegal payments or gifts to physicians.

In an effort to prevent these types of situations, many academic medical centers, professional societies, medical journals, and other institutions have adopted stronger policies on conflict of interest.

In 2007, the Institute of Medicine (IOM) appointed the Committee on Conflict of Interest in Medical Research, Education, and Practice to examine conflicts of interest in medicine and to recommend steps to identify, limit, and manage conflicts of interest without negatively affecting constructive collaborations. The committee's report stresses the importance of preventing bias and mistrust rather than trying to remedy damage after it is discovered. This report specifically focuses on financial conflicts of interest involving pharmaceutical, medical device, and biotechnology companies.

The committee recommends that medical institutions establish conflict of interest policies that require disclosure and management of both individual and institutional financial ties to industry.

DISCLOSING AND ASSESSING FINANCIAL RELATIONSHIPS

The committee recommends that medical institutions—including academic medical centers, professional societies, patient advocacy groups, and medical journals—establish conflict of interest policies that require disclosure and management of both individual and institutional financial ties to industry. Institutions should create con-

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flict of interest committees to evaluate these ties. If necessary, a board-level committee should deal with conflicts of interest at the institutional level, which typically arise when research conducted within an institution could affect the value of an institution's investments or patents.

Disclosure of financial relationships with industry is an essential, though limited, first step in identifying and responding to conflicts of interest. Because current policies are highly variable and sometimes confusing, the committee recommends standardizing the content, format, and procedures for disclosing financial relationships physicians and researchers have with industry. Such standardization will provide institutions with specific information they need to assess the severity of conflicts and to determine whether the relationship needs to be eliminated or actively managed. It will also simplify requirements for physicians and researchers who must disclose information to multiple institutions. Physicians, researchers, academic medical centers, professional societies, consumer and patient advocacy groups, medical journals, accreditation and certification organizations, licensing boards, other government agencies, and organizations with experience in database development and management should be involved in developing uniform disclosure standards.

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In addition to steps taken by the medical community, Congress should create a national reporting program that requires pharmaceutical, medical device, and biotechnology companies to make public all payments to physicians, researchers, health care institutions, professional societies, patient advocacy and disease groups, and providers of continuing medical education. Public reporting will enhance accountability by allowing academic medical centers, medical journals, and others to verify disclosures made to them by faculty members, article authors, and others.

IMPROVING CONFLICT OF INTEREST POLICIES IN MEDICAL RESEARCH, EDUCATION, AND PRACTICE

Although the committee recognizes that collaborations with industry can be beneficial, the committee recommends, as a general rule, that researchers should not conduct research involving human participants if they have a financial interest in the outcome of the research, for example, if they hold a patent on an intervention being tested in a clinical trial. The only exceptions should be if an individual's participation is judged to be essential for the safe and appropriate conduct of the research.

Financial relationships with industry are extensive in medical education. To reduce the risk for bias within the learning environment, academic medical centers and teaching hospitals should prohibit faculty from accepting gifts, making presentations that are controlled by industry, claiming authorship for ghost-written publications, and entering into consulting arrangements that are not governed by written contracts for expert services to be paid for at fair market value. Medical centers also should restrict visits by industry sales people and limit use of drug samples to patients who lack financial access to medications.

Many providers of accredited continuing medical education—a usual requirement for relicensure of physicians—receive the majority of their funding from industry. The report recommends a broad-based consensus process to develop a new system for funding high-quality accredited continuing medical education that is free of industry influence. The committee recognizes that such a system may involve higher costs for physicians and require cost-cutting steps by education providers.

Acceptance of meals and gifts and other relationships with industry are also common among physicians who practice outside medical centers. Data suggest that these relationships may influence physicians to prescribe a company's medicines even when evidence indicates another drug would be more beneficial. Therefore, the committee recommends eliminating these problematic relationships between physicians and industry. In addition, the committee recommends that community physicians should also follow the restrictions described previously regarding gifts, including meals, from companies; presentations or articles whose content is controlled by industry; meetings with sales representatives; and use of drug samples. Professional societies and health care facilities should adopt policies that reinforce this recommendation.

Clinical practice guidelines influence physician practice, quality measures, and insurance coverage decisions. Given this influence, clinical practice guidelines need to be developed with greater transparency and accountability. The committee recommends that professional societies and other groups that develop practice guidelines not accept direct industry funding for guideline development and generally exclude individuals with conflicts of interest from the panels that draft the guidelines. In addition, these groups should make public their conflict of interest policies, their funding sources, and any financial relationships panel members have with industry.

In order to promote the adoption of conflict of interest policies by institutions engaged in medical research, education, clinical care, or the development of practice guidelines, the report urges other organizations such as health insurers, accrediting bodies, and government agencies to develop incentives for policy change consistent with the recommendations in the committee's report. For example, health insurers and other organizations that use clinical practice guidelines should avoid using guidelines that were developed without strong conflict of interest protections.

The committee also recommends that the Department of Health and Human Services develop a research agenda to create a stronger evidence base for future conflict of interest policies. Such research should evaluate the impact of conflict of interest policies, including both desired outcomes and possible unwanted consequences.

Responsible and reasonable conflict of interest policies and procedures will reduce the risk of bias and the loss of trust while avoiding undue burdens or harms and without damaging constructive collaborations with industry.

CONCLUSION

Society traditionally has placed great trust in physicians and researchers, granting them the considerable leeway to regulate themselves. However, there is growing concern among lawmakers, government agencies, and the public that extensive conflicts of interest in medicine require stronger measures. Responsible and reasonable conflict of interest policies and procedures will reduce the risk of bias and the loss of trust while avoiding undue burdens or harms and without damaging constructive collaborations with industry. Decisions about biomedical research, medical education, and patient care directly affect the public's health. The public needs to be able to trust that physicians' decisions are not inappropriately influenced by their financial relationships with industry.

FOR MORE INFORMATION . . .

Copies of *Conflict of Interest in Medical Research, Education, and Practice* are available from the National Academies Press, 500 Fifth Street, N.W., Lockbox 285, Washington, DC 20055; (800) 624-6242 or (202) 334-3313 (in the Washington metropolitan area); Internet, www.nap.edu. The full text of this report is available at www.nap.edu.

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