Conflict of Interest in Medical Research, Education, and Practice

A Focus on Medical Research

Society relies upon research to advance scientific discoveries and develop new medications and medical devices to benefit both individual 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 research collaborations can benefit society, financial ties between medicine and industry can create significant risks that these interests will inappropriately influence professional judgments. Such conflicts of interest jeopardize the integrity of scientific investigations and also threaten the objectivity of professional education, the quality of patient care, and the public’s trust in medicine.

In 2007, the Institute of Medicine (IOM) appointed the Committee on Conflict of Interest in Medical Research, Education, and Practice 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 study focuses 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 report cites a number of situations that raise concerns about conflict of interest in research. Examples include:
- Research institutions failing to evaluate and respond to the risks posed when researchers have a financial stake in the outcome of their research
- Sponsors and academic investigators failing to publish negative results from industry-funded clinical trials or delaying publication for more than a year following completion of a trial
- Researchers failing to disclose financial relationships with industry to research institutions and sponsors, as required, for example when applying for Public Health Service (PHS) research funding

Principles for Conflict of Interest Policies

Conflict of interest policies seek to ensure that individual and institutional decisions serve professional and institutional goals and are not unduly influenced by

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competing interests, such as equity holdings in pharmaceutical or medical device companies. Disclosure of financial relationships is an essential first step in identifying and responding to conflicts of interest, which should be followed by an evaluation of the risk to determine if bias will occur or public trust in research will be undermined. Research institutions then should determine whether the research is allowed to proceed, or whether additional measures, such as further disclosure, management of the relationship, or prohibition, are warranted. The report proposes several criteria for institutions to use when assessing conflict of interest policies.

- **Proportionality:** Is the policy effective, efficient, and directed at the most important and most common conflicts?
- **Transparency:** Is the policy comprehensible and accessible to the individuals and institutions that may be affected by it?
- **Accountability:** Does the conflict of interest policy indicate who is responsible for monitoring, enforcing, and revising it?
- **Fairness:** Does the policy apply equally to all relevant groups within an institution and in different institutions?

### IMPROVING CONFLICT OF INTEREST POLICIES IN MEDICAL RESEARCH

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 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.

Although individual and institutional conflict of interest policies should cover all biomedical research, clinical research raises special concerns since it could harm research participants and result in compromised findings submitted to the Food and Drug Administration for approval of drugs or devices, and subsequent harm to patients.

Therefore, the committee recommends that 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. 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.

Compared to clinical research, conflicts of interest in 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 com-
mittee suggests that 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.

**ADDITIONAL STEPS TO IMPROVING CONFLICT OF INTEREST POLICIES**

Several other recommendations by the committee have important implications for research. Because current policies are highly variable in their requirements for disclosure, the IOM committee recommends that organizations representing academic medical centers, such as the Association of American Medical Colleges, as well as physicians, researchers, and research sponsors work together to develop consensus on standard content, format, and procedures for the disclosure of financial relationships. Such a disclosure policy would provide institutions with sufficient information to assess the severity of conflicts and reduce the administrative burden on physicians and researchers who must disclose financial information to multiple institutions.

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 program requiring pharmaceutical, medical device, and biotechnology companies to publicly report payments to physicians, researchers, health care institutions, professional societies, patient advocacy and disease-specific groups, and providers of continuing medical education. Such public reporting will enhance accountability, allowing universities, journals, and other organizations to verify disclosures made to them by researchers and others.

In order to promote the adoption of conflict of interest policies, the IOM committee urges organizations such as medical journals, professional societies, and government agencies to develop incentives that encourage medical institutions to adopt and implement policies consistent with these recommendations. 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 include evaluations of conflict of interest policies, including desired outcomes and possible unintended adverse consequences.

**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. 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.
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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