

IOM Releases Report Addressing Potential Conflicts of Interest Between Industry and the Medical Community

On April 28, 2009, the Institute of Medicine (IOM) released a report, entitled *Conflict of Interest in Medical Research, Education, and Practice*, that examines the potential conflicts of interest arising from the relationship between the pharmaceutical, medical device and biotechnology industry and the medical community. The IOM report addresses many issues covered by the recent revisions made to pharmaceutical and medical device industry codes and echoes recommendations from the June 2008 report of the Association of American Medical Colleges (AAMC) that addressed industry funding for medical education. However, by its own account, the report is broader in both its application “across the entire spectrum” of the medical community and in its identification of overarching principles for assessing and disclosing conflicts of interest. Click [here](#) for a copy of the IOM press release summarizing highlights of the report.

Overview

The 353-page report contains 16 recommendations aimed at improving transparency and ending practices that may cause the public to question the integrity of medical research, the objectivity of continuing medical education, and the legitimacy of clinical practice guidelines. In making these recommendations, the IOM seeks to strike a balance between restricting practices that allegedly “threaten the integrity of the medical profession and erode public trust” without eliminating what the authors believe to be constructive collaboration among medical research and education institutions, institutions engaged in clinical care, and entities engaged in the development of clinical practice guidelines.

Recommendations

In developing its recommendations, the IOM reviewed much of the available evidence on the interactions between industry and physicians and researchers. From this evidence, the IOM made both broad recommendations that apply across the entirety of the medical community as well as specific recommendations applicable to different types of institutions, such as academic medical centers. Some of the major issues addressed by the IOM report include:

- **Development of Standard Conflict of Interest Policies.** The IOM notes wide variations in current policies governing conflicts of interest and disclosure of financial relationships with industry among institutions that carry out medical research and education, clinical care, and clinical practice guideline development. A central tenet of the IOM report is that these institutions should adopt conflict of interest policies consistent with the other recommendations made in the report and engage in a consensus process to develop standard content, format, and procedures for the disclosure of financial relationships with industry.
- **Public Reporting of Payments.** The IOM report recommends that Congress enact a national disclosure program to ensure that pharmaceutical, medical device, and biotechnology companies (and their foundations) publicly report payments to a broad range of recipients. Unlike the Physician Payment Sunshine Act of 2009, as proposed by Senators Chuck Grassley and Herb Kohl, which by its terms applies only to physicians, physician medical practices, and physician group practices, the IOM asks Congress to require public reporting on payments to researchers, institutions, professional societies, patient advocacy and disease specific groups, and providers of medical education.

The IOM views mandatory national disclosure as helpful to increasing accountability for the accuracy of institution-based disclosures.

- **Gifts, Meals, and Ghostwriting.** Similar to the AAMC Report, the IOM recommends that academic medical centers prohibit faculty and students from accepting any meals or gifts from industry, making speaker bureau presentations that are controlled by industry, and claiming authorship for ghostwritten publications. It is the opinion of the IOM that these activities create undue influence by industry and undermine the goals of medical education that greatly outweigh any possible educational benefit to faculty or students.
- **Access.** The IOM also calls for academic medical centers to create policies that limit site access by drug and medical device sales representatives, except by faculty invitation in certain specified situations. Together with the AAMC Report, these IOM recommendations may accelerate the adoption of, and bring uniformity to, the access restrictions currently being implemented by many medical institutions on an ad hoc basis.
- **Samples.** The IOM calls for academic medical centers and community physicians to oversee and restrict the receipt of drug samples from sales representatives. It is the belief of the IOM that similar to other gifts, the acceptance of drug samples presents difficult conflict of interest issues, encourages the use of brand name drugs, and does not often provide increased access to medications to indigent patients.
- **Continuing Medical Education.** The report also recommends convening a broad-based development process to propose a new funding system that would make continuing medical education free from industry influence within 24 months. The IOM recognizes that this recommendation would likely increase costs of attending accredited continuing medical education programs, which may become an “economic burden” for some physicians; however, the report states that these steps are necessary to enhance “integrity of the system” and provide a high-quality education.

Greater Implications of the IOM Report

The IOM report does not have the force of law nor does it require any change in practices. However, the IOM’s findings and recommendations will likely have an impact on the health care reform debate by serving as a resource for both members of Congress and thought leaders of academic medicine as they seek to redefine the appropriate relationship between the medical community and industry. In addition, the report’s observations and recommendations for improving disclosure and transparency regarding potential conflicts of interest are likely to influence health care institutions and health care-related advocacy groups in the development and revision to their own conflict of interest policies.

Contact Information

Our Life Sciences and Health Care practice groups are developing a more comprehensive overview of how the recommendations made in the IOM Report, if implemented, would affect existing industry codes, reports, and guidance that address similar subject matter. If you have any immediate questions about the IOM report or are interested in receiving a copy of the overview when available, please contact your regular Ropes & Gray lawyer.

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