IOM Issues Report to Curb Conflicts of Interest

BY MARY ELLEN SCHNEIDER

Physicians should stop accepting gifts or meals from industry representatives, according to a new report from the Institute of Medicine that offers 16 recommendations aimed at limiting financial conflicts of interest in medicine.

While some relationships with industry are beneficial, the widespread industry ties that have become common among physicians and researchers could undermine public confidence in medicine, according to the report from the IOM Committee on Conflict of Interest in Medical Research, Education, and Practice.

"This is a vital issue that really goes to the heart of patients' trust that they are receiving the best medical advice and medical care," Dr. Bernard Lo, chair of the IOM committee and director of the program in medical ethics at the University of California, San Francisco, said during a press briefing.

In a 300-plus page report, the IOM committee provides recommendations for physicians and institutions to identify and manage financial conflicts of interest in medical research, education, and practice. The report focuses specifically on financial relationships with pharmaceutical, medical device, and biotechnology companies.

For starters, all institutions engaged in medical research, education, and practice should establish conflict of interest policies that require all physicians, researchers, and senior officials to disclose their ties to industry. The committee also recommended that the medical community come together to create a universal, standardized, electronic disclosure form to cut down on variation and reduce administrative burdens for physicians.

Beyond these voluntary disclosure ef-

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forts, the IOM committee recommended that Congress require drug and device makers and industry foundations to publicly report any payments to physicians, researchers, health care institutions, professional societies, patient advocacy and disease groups, continuing medical education (CME) providers, and related foundations.

This type of searchable public database would allow medical institutions and journal publishers to verify the disclosure information they receive from researchers and physicians, the committee said.

While disclosure of financial ties was a major focus of the committee's recommendations, it was only the beginning. Institutions also must act to prohibit certain relationships with industry and strictly manage others, Dr. Lo said. "Disclosure is a necessary first step, but it's a limited first step," Dr. Lo said. "If you don't disclose relationships to the institution you work for, they can't figure out what to do."

In addition to refusing to accept gifts and meals from industry, the IOM committee recommended that physicians set restrictions on their contacts with sales representatives and use drug samples only for patients who can't afford medications. The committee also recommended that physicians enter into only bona fide consultation arrangements with industry provided that these include written contracts and that physicians avoid presenting or publishing any material whose contract is controlled or ghostwritten by industry. The report includes similar recommendations for faculty, students, residents, and fellows at academic medical centers.

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The report also addressed industry influence in the development of clinical practice guidelines. The committee recommended that groups involved in guideline development not accept direct funding from industry. Additionally, they should try to exclude individuals with conflicts of interest from serving on guideline development panels. If the necessary expertise can't be obtained from experts who are free of conflict, the IOM committee advised that conflicted individuals should be a minority on the panel and should be barred from voting on any topics in which they have a financial interest. The committee also recommended that the chair of the guideline panel be free of conflicts.

In the research arena, the IOM committee recommended that, in general, investigators should not conduct research involving human subjects if they have a financial stake in the outcome of the study. Exceptions are possible but should be made only if the researcher's participation is considered essential to the safety of the research. And, even then, a conflict of interest committee should approve the involvement and consider placing restrictions on his or her role in the study, according to the committee's recommendations.

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The Pharmaceutical Research and Manufacturers of America (PhRMA) was still reviewing the IOM report at press time. However, the group cautioned policy makers and the medical community to balance the need to manage potential conflicts of interest against the possibility that "overly restrictive policies" could have unintended consequences. For example, prohibitions on the use of drug samples or on industry funding for continuing medical education could negatively affect patient care, according to the group.

"In the end, interactions between pharmaceutical sales representatives and health care professionals enhance public health and improve patient care," Ken Johnson, PhRMA senior vice president, said in a statement. "Pharmaceutical research companies take this responsibility seriously and remain committed to ensuring that these interactions follow the highest standards."

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The report is available online at www.nap.edu/catalog.php?record_id=12598#toc.