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VOLUNTARY AND REGULATORY MEASURES NEEDED TO REDUCE CONFLICTS OF INTEREST IN MEDICAL RESEARCH, EDUCATION, AND PRACTICE

WASHINGTON - New voluntary and regulatory measures can strengthen protections against financial conflicts of interest in medicine without hindering patient care or the advancement of medical knowledge, says a new report by the Institute of Medicine.

The report tackles conflicts of interest across the spectrum of medicine, from biomedical research to clinical care and from the training of new doctors to the continuing education of physicians. It recommends several actions to improve disclosure of financial ties between the medical community and industry, limit company payments and gifts, and remove industry influence from medical education and the development of practice guidelines.

"It is time to end a number of long-accepted practices that create unacceptable conflicts of interest, threaten the integrity of the medical profession, and erode public trust while providing no meaningful benefits to patients or society," said Bernard Lo, chair of the committee that wrote the report and professor of medicine and director of the program in medical ethics, University of California, San Francisco. "We also need more specific disclosure of the financial relationships that doctors and researchers have with medical industries.

This report spells out a strategy to protect against financial conflicts while allowing productive relationships between the medical community and industry that contribute to improved medical knowledge and care."

All academic medical centers, journals, professional societies, and other entities engaged in health research, education, clinical care, and development of practice guidelines should establish or strengthen conflict-of-interest policies, the report says.

Disclosure by physicians and researchers not only to their employers but also to other medical organizations of their financial links to pharmaceutical, biotechnology, and medical device firms is an essential first step in identifying and managing conflicts of interest and needs to be improved.

The committee noted substantial variations in institutions' conflict-of-interest policies and shortcomings in physicians' and researchers' adherence to policy requirements. The format for disclosure and categories of relationships should be standardized to help institutions judge the risk that a relationship poses and to ease the burden for individuals who must report information to multiple organizations with different policies.

In addition, Congress should require pharmaceutical, biotechnology, and device firms to report through a public Web site the payments they make to doctors, researchers, academic health centers, professional societies, patient advocacy groups, and others involved in medicine. A public record like this could serve as a deterrent to

inappropriate relationships and undue industry influence. It also would provide medical institutions with a way to verify the accuracy of information that physicians, researchers, and senior officials have disclosed to them.

The report calls on researchers, medical school faculty, and private-practice doctors to forgo gifts of any amount from medical companies and to decline to publish or present material ghostwritten or otherwise controlled by industry. Consulting arrangements should be limited to legitimate expert services spelled out in formal contracts and paid for at a fair market rate. Physicians should limit their interactions with company sales representatives and use free drug samples only for patients who cannot afford medications. Several professional organizations and industry groups have set new limits on gift giving and other relationships between industry and the medical community, but it is too soon to gauge the effects these changes, the committee noted.

Greater transparency and accountability are needed in the development of clinical practice guidelines, which advise physicians on how to best provide care. Groups that develop guidelines should not accept direct industry funding for this work and generally should exclude individuals with conflicts of interest from the panels that draft guidelines, the report says. In addition, the current system for financing accredited continuing medical education relies too heavily on industry support and needs to be overhauled to be free of industry influence and provide high-quality education.

Professional societies, government agencies, and the groups that accredit medical schools can encourage adoption and implementation of conflict-of-interest policies by publicizing which institutions have adopted the recommended policies and which have not. This publicity could motivate institutions to close gaps in their conflict-of-interest policies or to justify why they disagree with the recommendations. For example, groups that accredit and certify medical schools could set standards for the adoption of conflict-of-interest policies and publicly list the institutions that follow those standards. Similarly, the World Association of Medical Editors could publicize which journals have adopted authorship and other policies consistent with its conflict-of-interest statements. The report also calls for more research on the impact of conflict-of-interest policies so that future policies can be based on more rigorous evidence.

Although the report calls for some new legislation and regulations, it also emphasizes the role of voluntary efforts by medical groups, industry, and individual professionals. Voluntary action is more likely to reinforce professional values and foster policies that minimize unintended consequences and administrative burdens. However, the report warns, if the industry and the medical community fail to strengthen their conflict-of-interest policies, practices, and enforcement, more policymakers may turn to legislative

solutions, as officials in some states have.

Interactions between industry and the medical community have evolved over decades, becoming commonplace today and producing both benefits and concerns. Research collaborations have yielded new cancer drugs, HIV/AIDS therapies, prosthetic heart valves, tools to monitor anesthesia, and many other advances in the prevention, diagnosis, and treatment of illness, the report notes. At the same time, legal and media investigations into relationships between industry and the medical community have led to embarrassing revelations about lack of disclosure and dubious relationships, congressional legislative proposals, and prosecutions. Although data are limited on the extent to which conflicts result in biased decision making or harm, such conflicts can erode trust in doctors and the research enterprise, the report concludes.

The study was sponsored by the National Institutes of Health, Robert Wood Johnson Foundation, Greenwall Foundation, ABIM Foundation, Burroughs Wellcome Fund, and Josiah Macy Jr. Foundation. Established in 1970 under the charter of the National Academy of Sciences, the Institute of Medicine provides independent, objective, evidence-based advice to policymakers, health professionals, the private sector, and the public. The National Academy of Sciences, National Academy of Engineering, Institute of Medicine, and National Research Council make up the National Academies. A committee roster follows.

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Copies of Conflicts of Interest in Medical Research, Education, and Practice are available from the National Academies Press; tel. 202-334-3313 or 1-800-624-6242 or on the Internet at <http://www.nap.edu>. Reporters may obtain a copy from the Office of News and Public Information (contacts listed above). In addition, a podcast of the public briefing held to release this report is available at <http://national-academies.org/podcast>.