



Statement

of the

American Medical Association

to the

**Special Committee on Aging
United States Senate**

**RE: Paid to Prescribe?: Exploring the
Relationship Between Doctors and the
Drug Industry**

Presented by: Robert M. Sade, MD

June 27, 2007

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The American Medical Association (AMA) appreciates the opportunity to provide its views regarding the ethics that govern the interactions between physicians and the pharmaceutical industry. We commend Chairman Kohl, Ranking Member Smith, and members of the Committee for convening this hearing to examine financial relationships between physicians and the pharmaceutical industry that, if inconsistent with accepted medical ethics, could affect physician prescribing behaviors. I am Robert M. Sade, MD, Chairman of the AMA's Council on Ethical and Judicial Affairs (CEJA). I am also Professor of Surgery and Director of the Institute of Human Values in Health Care at the Medical University of South Carolina in Charleston.

The AMA has clear ethical guidelines that govern physician interaction with the pharmaceutical industry. In brief, based on the AMA Principles of Medical Ethics (Principles) and the AMA Code of Medical Ethics (AMA Code), physicians' responsibility to their patients is paramount. This means that physicians must not place their own financial interests above the welfare of their patients and their medical recommendations must not be inappropriately influenced by financial considerations. Accordingly, it is unethical for a physician to unnecessarily prescribe a drug for financial benefit; rather prescriptions must be based on the best medical interests of patients. This requires that physicians' prescribing be consistent with the latest scientific information and consistent with the physician's best medical judgment.

In support of these standards, approximately six years ago the AMA undertook a major campaign to educate physicians and representatives of the pharmaceutical, device, and medical equipment industries about the AMA's ethical guidelines regarding promotional gifts to physicians from the industry. In launching this educational initiative, the AMA

was joined by more than 30 other physician and health care organizations and corporations, which came together to form the Working Group on the Communication of Ethical Guidelines for Gifts to Physicians from Industry. As a result of this collaboration, the AMA designed an awareness program to sensitize the various stakeholders concerning ethical guidelines and developed an educational program that includes four modules that address issues typically arising in this area.

Physician prescribing decisions are heavily dependent on the quality of the scientific information available, provided to them, in part, by industry and federal regulators. There is a clear need for interactions between physicians and the pharmaceutical industry to ensure the free flow of valid scientific information. When the information is accurate and complete, physicians have the necessary tools to make the right prescribing decisions. If information is not properly provided by industry, or if physicians never receive such information, necessary and appropriate medical care can be jeopardized.

Within this context, the AMA has developed ethical standards to guide physicians in their interactions with industry, particularly in relation to the direct interaction of pharmaceutical representatives with physicians.

AMA Principles of Medical Ethics & Code of Medical Ethics

The AMA was founded with the purpose of establishing ethical standards for all physicians. First developed in 1847, the AMA Code undergoes continual revision, as guided by CEJA. The opinions contained in the AMA Code address relevant issues in medical practice that establish core standards of conduct for the medical profession. The AMA Code constitutes the most comprehensive source of ethical guidance for physicians and serves as the primary compendium of medical professional ethical statements in the United States.

Jurisdiction and Scope of CEJA

CEJA is composed of seven practicing physicians, a resident or fellow, and a medical student. The members are nominated by the AMA's President and elected by the AMA's House of Delegates. CEJA prepares reports that analyze timely ethical issues confronting the medical profession and makes recommendations to guide physician behavior. When these reports are adopted, its recommendations become the opinions that constitute the AMA Code.

In addition to its responsibility to maintain and update the AMA Code, CEJA has judicial responsibilities, which include jurisdiction over membership in the AMA to ensure compliance with the AMA Code. CEJA does not have explicit authority to investigate non-member physicians. However, many state medical licensing boards use the AMA Code to establish standards of physician conduct and courts look to the AMA Code for guidance in resolving disputes involving physicians. Thus, the reach of the AMA Code extends throughout the medical profession. The AMA Code, therefore, is a key element in the medical profession's commitment to ethical conduct, and its reach goes well beyond its direct influence on AMA members. However, professional self-regulation cannot be fully accomplished by a single institution; it requires the collaboration of other

bodies. While the AMA establishes ethical standards, it works in concert with state medical associations and specialty societies to disseminate the information. To ensure compliance with these standards, the AMA relies not only on CEJA, but also on medical licensing boards.

CEJA & AMA Code

There opinions in the AMA Code are relevant to governing the interactions between physicians and the pharmaceutical industry. They establish an ethical framework that guides physicians in matters of conflicts of interest, gifts from industry, and appropriate factors to consider when prescribing drugs. In addition, physicians have an ongoing professional obligation to remain informed and knowledgeable about drug treatment options for patients, so the AMA Code has ethical guidance concerning continuing medical education (CME), as well.

Conflicts of Interests

The broadest provision governing conflicts of interest clearly states that physicians must subordinate reward or financial gain to their paramount responsibility to their patients.. If a conflict develops between the physician's financial interest and the physician's responsibilities to the patient, the AMA Code unambiguously requires that the conflict must be resolved in a manner that benefits the patient.

Gifts from Industry

The AMA Code acknowledges that the giving of gifts reflects a customary social practice; however, it warns that gifts to professionals, such as physicians, from commercial businesses, such as pharmaceutical companies, may not be consistent with the AMA Code. To avoid accepting inappropriate gifts, physicians must comply with a number of guidelines. Among the salient guidelines, gifts accepted by physicians should primarily entail a benefit to patients or be related to the physician's work and should not be of substantial value. Also, the AMA Code explicitly provides that no gifts should be accepted if there are conditions attached. For example, physicians should not accept gifts that depend on the physician's prescribing practices or that establish expectations that may influence the patient-physician relationship. All gifts are not inappropriate. Indeed, many of them will inure primarily to the benefit of patients. An example is the practice of physicians providing drug samples to patients who would not otherwise have access to necessary drugs. This provides a clear and direct benefit to patients who have a medically indicated need for treatment, but lack the resources to obtain the necessary care. Physicians are on the front lines and know first hand the importance of gifts from pharmaceutical representatives in the form of free samples.

Prescribing Drugs

The AMA Code contains a specific requirement that concerns the obligations that physicians have when prescribing drugs. It provides that physicians should prescribe drugs based solely upon medical considerations, patient need and reasonable expectations of the effectiveness of the drug for the particular patient. This standard reemphasizes that physicians may not accept any kind of payment or compensation from a pharmaceutical company as a *quid pro quo* for prescribing its products.

Continuing Medical Education

Like physician prescribing, the AMA also has guidelines designed to help frame how industry may support educational activities certified for Continuing Medical Education (CME) credit for physicians. The AMA Code provides that physicians should strive to further their medical education throughout their careers because only through participation in CME can physicians continue to serve patients to the best of their abilities and maintain professional standards of excellence. CME consists of educational activities that serve to maintain, develop, or increase the knowledge, skills, and professional performance and relationships that a physician uses to provide services for patients or the profession. CME is based on a body of knowledge or skills generally accepted by the profession as within the basic medical sciences and clinical medicine, as well as the provision of health care to the public. Most state medical licensing boards, acting under the state's medical practice act, require physicians to complete a certain amount of CME every year. Additionally, several national specialty societies require CME credits to maintain membership. Generally CME credit indicates that the educational event is a meritorious learning activity sponsored by an accredited organization.

Guidance pertaining to CME activities is derived from one of the nine AMA Principles of Medical Ethics: a physician has an affirmative obligation to “continue to study, apply, and advance scientific knowledge, [and to] maintain a commitment to medical education...” Subsidies to underwrite the costs of CME can contribute to the improvement of patient care and therefore are permissible. However, industry subsidies to underwrite the costs of certified educational activities must not undermine the foregoing ethical commitment. As a result, subsidies should not be granted in a manner that compromises the medical profession's control over the selection of content, faculty, educational methods, and materials. Because a company's representative giving a subsidy directly to a physician may create a relationship that could inappropriately influence the use of the company's products, any subsidy should be accepted by the CME provider instead. In turn the accredited CME provider may use the funds to reduce the accredited educational activity cost for all participants. Payments from a company should not be accepted directly by physicians attending a CME activity.

Physicians serving as presenters, moderators, or other faculty at a CME conference should ensure that research findings and therapeutic recommendations are based on scientifically accurate, up-to-date information and are presented in a balanced, objective manner. Faculty must ensure that the content of their presentation is not modified or influenced by industry or other financial contributors. All conflicts of interest, such as a financial connection to a particular commercial firm or product, should be disclosed by faculty members to the CME provider and to the audience. Faculty may accept reasonable honoraria and reimbursement for expenses.

Physicians involved in organizing CME activities should ensure that the program is balanced, with faculty members presenting a broad range of scientifically supportable viewpoints related to the topic at hand. Any non-CME activity that is primarily

promotional must be identified as such to faculty and participants, both in its advertising and at the conference itself.

The AMA has worked with health care stakeholders—including the Food and Drug Administration (FDA) and the U.S. Department of Health & Human Services' Office of the Inspector General (OIG)—on concepts of content independence for certified educational activities through the National Task Force on CME Provider-Industry Collaboration. Currently, the AMA chairs the Task force which meets annually. Over the years, the faculty has included representatives of the FDA, the OIG, the Accreditation Council for Continuing Medical Education (ACCME), the American Academy of Family Physicians (AAFP), and CEJA, among others, to address issues related to physician and CME provider interactions with industry. The materials from the Task Force annual meetings are often made available at another key meeting, the Alliance for Continuing Medical Education annual meeting, as well.

AMA Educational Initiatives

Continuing education is critical to ensure that physicians identify and resolve possible conflicts of interest that may interfere with the integrity and independence of a certified CME activity. In addition to the AMA's participation with the Working Group on the Communication of Ethical Guidelines for Gifts to Physicians, the AMA has provided substantial ongoing support for the work of the National Task Force on CME Provider and Industry Collaboration. Equally important to the foregoing initiatives, five years ago, the AMA communicated to all medical schools and residency programs the importance of including education on ethical guidelines regarding gifts to physicians from industry within their curricula. The AMA also recommended to all medical school deans and residency program directors that appropriate policies be developed for medical students, residents, and faculty regarding the issue of gifts to physicians from industry. Four years ago, *Virtual Mentor*, the online AMA Journal of Ethics visited by tens of thousands of medical students and medical educators every month, devoted an entire issue to interactions with the drug industry. These articles are continuously available online to anyone seeking information related to this topic.

The AMA is currently developing a series of educational programs for medical students and physicians to promote the importance of sound prescribing. Partly funded by the state Attorneys General of the United States. These programs build on previous AMA efforts to educate physicians about their ethical responsibilities in making cost-effective prescribing decisions and how they can minimize and eliminate undue influence by industry marketing and promotional practices. Special attention is given to the next generation of physicians—medical students and resident physicians—in addressing this important issue, especially because interactions with industry often start very early in a physician's professional career. The AMA is committed to educating physicians about sound prescribing from their first days in medical schools to their last day in clinical practice. The health and welfare of patients depend on it.

In sum, interactions between industry and the medical profession must be defined by the exchange of sound scientific information, which benefits patients. All practices that

surround those encounters, from the visits of pharmaceutical representatives to a physician's office to large educational gatherings, must be framed in terms of such an exchange and must not constitute an attempt to inappropriately influence the medical treatment that physicians provide to patients.

The AMA, along with other stakeholders in the medical profession, continues to take appropriate measures to reduce the actual or perceived conflicts-of-interest that might arise from gifts from industry to physicians, in order to safeguard the delivery of quality health care based on the best available science, thus earning and maintaining the trust of patients.

The AMA appreciates the opportunity to provide our views to the Special Committee On Aging on the relevant ethical principles and AMA Codes that govern physician interactions with the pharmaceutical industry.