REPORT OF THE COUNCIL ON ETHICAL AND JUDICIAL AFFAIRS

CEJA Report 4-I-08

Subject: Informed Consent in Investigational Trials

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At its 2008 Annual Meeting, the American Medical Association (AMA) House of Delegates adopted Resolution 12 (A-08), "Medical Ethical Guidelines for Informed Consent in Investigational Trials." This resolution asks that the AMA's Council on Ethical and Judicial Affairs (CEJA) "review the physician investigator's obligation to inform patients of potential conflicts of interest in recommending patients for or the conduct of a proposed research study." For reasons set forth below, CEJA has determined that its current policies address the issues raised by the resolution.

This resolution concerns the basic ethical duty of physicians to respect the autonomous decision-making of their patients while facilitating the communication of information, discussion of appropriate treatment options, and offering guidance on an optimal course of action. In their role as investigators, physicians should help maintain public trust by, among others, a commitment to "transparency in the design, execution, and reporting of research" (E-2.078).

Consistent with the above duties, Opinion 8.0315, "Managing Conflicts of Interest in the Conduct of Clinical Trials," provides some specific guidance. It clearly states that "the nature and source of funding and financial incentives offered to the investigator must be disclosed to a potential participant as part of the informed consent process" (Guideline 6). Additional recommendations for the management of conflicts of interest include rejecting payments solely for referring patients to research studies (Guideline 4 and Opinion 6.03, "Fee Splitting: Referrals to Health Care Facilities"), declining financial compensation that is dependent on participant enrollment volume or exceeds fair market value (Guideline 4), and ensuring that someone other than the treating physician is seeking consent from patients who are eligible to enroll in a clinical trial that the treating-physician is conducting (Guideline 3).

Therefore, physicians have an ethical duty to appropriately manage any financial conflicts of interest that may interfere with their ability to facilitate the autonomous decision-making of potential research participants. Disclosing to participants the nature and source of funding and financial incentives is one important means of managing potential conflicts of interest in conducting or referring patients for proposed research studies.

In light of these provisions, the Council believes that there is adequate ethics policy in this area at the present time.