REPORT OF THE COUNCIL ON ETHICAL AND JUDICIAL AFFAIRS*

CEJA Report 2-I-13

Subject: Amendment to E-8.061, "Gifts to Physicians from Industry"

Presented by: Susan Dorr Goold, MD, Chair

Referred to: Reference Committee on Amendments to Constitution and Bylaws

(Larry E. Reaves, MD, Chair)

Opinion E-8.061, "Gifts to Physicians from Industry," was originally issued in 1992 to provide guidance for physicians in their relationships with industry in clinical practice. The American Medical Association (AMA) was a pioneer in turning physicians' attention to the ethical concerns posed by gifts from industry. However, medicine-industry relationships have evolved significantly since E-8.061 was last updated in 1998 and so has public and professional unease about the possibility that gift relationships between physicians and pharmaceutical, medical device and equipment, and biotechnology companies will have inappropriate effects. Over the intervening years empirical research has explored the question of gift relationships and other organizations have reflected on the ethical implications and issued policies in this area, many of which have built on the foundations of E-8.061. As it stands, E-8.061 no longer represents best thinking with respect to gifts to physicians from industry. The Council on Ethical and Judicial Affairs (CEJA) has thus concluded that this opinion should be updated.

THE CURRENT ETHICAL CONSENSUS

Since CEJA's original report, concerns about physicians' relationships with industry, including the acceptance of gifts, have continued to grow as evidence has accumulated about the influence of such relationships on physician practice.[1-5] A consensus has emerged over the past decade or so that recognizes the enormous value of maintaining strong relationships between medicine and industry, notably in research and innovation, but equally recognizes the need for circumspection where gifts to individual physicians are concerned. This is the case whether gifts are large or small, financial or in-kind, office supplies or patient educational materials.[6-8]

Calls for physicians to decline industry gifts of any size or nature have become prominent among many scholars of medicine-industry relationships, [2,3,9] in reports by distinguished national bodies, [4,5] and among national professional organizations and in advocacy campaigns. [10-12] In 2007, the American Medical Student Association began surveying the conflict of interest policies of all allopathic medical schools in the U.S. to create its "PharmFree Scorecard," scoring medical schools with respect to their policies on gifts and pharmaceutical samples, among other domains. [13] In 2008 the Association of American Medical Colleges urged academic medical centers to "establish and implement policies that prohibit the acceptance of any gifts from industry

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- by physicians and other faculty, staff, students, and trainees."[4] The following year, in its report 1 2 on conflicts of interest in medicine, the Institute of Medicine similarly recommended that all 3 physicians decline "items of material value" from industry and urged professional societies to 4 amend their policies to support its recommendations. 5 The Pharmaceutical Research & Manufacturers Association (PhRMA) 2008 Code on Interactions with Healthcare Professionals bans noneducational and practice-related gifts (other than samples), 6 7 items intended for the physician's personal benefit, and cash or cash-equivalents other than 8 compensation for bona fide services, though it permits "items designed primarily for the education of patients or healthcare professionals" valued at under \$100.[14] The 2009 Code of Ethics of the 9 10 Advanced Medical Technology Association (AdvaMed) similarly restricts gifts to physicians.[15] 11 12 According to data collected for AMSA's most recent "PharmFree Scorecard," 73 of 149 U.S. 13
 - medical schools responding to the survey now prohibit gifts from industry entirely, while another 36 have policies restricting acceptance of gifts in various ways.[13]

PROTECTING PATIENTS' INTERESTS & PUBLIC TRUST

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Patients must be able to trust that their physicians have based treatment recommendations on the physician's independent professional judgment and knowledge of the patient's unique circumstances. Gifts from industry can undermine physicians' objectivity and put at risk physicians' ability to fulfill their primary professional commitment to serve patients' interests.

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RECOMMENDATION

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In light of these considerations, the Council on Ethical and Judicial Affairs recommends that Opinion E-8.061, "Gifts to Physicians from Industry," be amended by substitution as follows, its accompanying clarification be rescinded, and the remainder of this report filed:

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Relationships among physicians and professional medical organizations and pharmaceutical, biotechnology, and medical device companies help drive innovation in patient care and contribute to the economic well-being of the community to the ultimate benefit of patients and the public. However, an increasingly urgent challenge for both medicine and industry is to devise ways to preserve strong, productive collaborations at the same time that they take clear effective action to prevent relationships that damage public trust and tarnish the reputation of both parties.

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Gifts to physicians from industry create conditions that carry the risk of subtly biasing—or being perceived to bias—professional judgment in the care of patients.

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To preserve the trust that is fundamental to the patient-physician relationship and public confidence in the profession, physicians should:

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(a) Decline cash gifts in any amount from an entity that has a direct interest in physicians' treatment recommendations.

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(b) Decline any gifts for which reciprocity is expected or implied.

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(c) Accept an in-kind gift for the physician's practice only when the gift:

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(i) will directly benefit patients, including patient education; and

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	(ii) is of minimal value.
(d)	Academic institutions and residency and fellowship programs may accept special
	funding on behalf of trainees to support medical students', residents', and fellows'
	participation in professional meetings, including educational meetings, provided:
	(i) the program identifies recipients based on independent institutional criteria; and
	(ii) funds are distributed to recipients without specific attribution to sponsors.
(Modify HO	DD/CEJA Policy)
Fiscal Note	e: Less than \$500 to implement.
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