



American College of Medical Genetics

Medical Genetics: Translating Genes Into Health®

Conflict of Interest

Statement of Principle

The potential that both real and perceived conflicts of interest might affect medical treatment and policy decisions has recently led to increased scrutiny in both the academic and public communities. Although there is a potential for many different types of conflict of interest that can occur for physicians and other health care providers, the one area that has received the most public scrutiny recently concerns the relationship between physicians and industry, primarily pharmaceutical and medical device companies. A recent JAMA publication in this regard (Rothman et al. "Professional Medical Associations and Their Relationships with Industry", JAMA. 2009; 301(13): 1367-1372) led to the formation of an ad hoc committee to examine areas of potential conflict of interest between industry and the American College of Medical Genetics ("the College") as discussed in that article. This document represents the satisfaction of that charge.

In its deliberations, the committee recognized that the specialty of Medical Genetics has some unique features as compared with many other medical specialties. The number of genetics healthcare professionals is relatively small, and includes M.D. and Ph.D. geneticists and genetic counselors who are either academically based or employed by industry. Nevertheless, the issues raised in the JAMA article are relevant to the College and its members and must be addressed. The committee also recognized that in addition to the potential conflicts of interest that may arise from financial relationships with industry, there are other relationships that could lead to either perceived or real conflicts of interest for the College and its members, i.e., serving on a medical advisory panel or advocacy group for a rare condition, directing an academically-based service-oriented diagnostic laboratory, or leading the effort to raise awareness for a medical condition that serves as the member's main area of academic interest that could lead to professional advancement. Given the committee's charge, this document will focus on relationships with industry. Relationships that members have that could lead to either perceived or real conflicts of interest for the College must be disclosed and discussed prior to engaging in any relevant activities of the College.

In the instance of diseases/disorders which are rare or very rare, the evidence base may be limited or even lacking. The experience and expert opinion of those few professionals who deal with such diseases is critical to the development of appropriate guidelines and procedures for the diagnosis, management, and treatment of affected patients. Therefore, the ACMG will not exclude from membership on the committees of the College, or restrict from appropriate participation in the activities of those committees, members who are employed by industry, recognizing the expertise and experience of such members and their valued and continuing service to the College. It is the consensus of the ad hoc committee that the College now has in place mechanisms for identifying and dealing effectively with conflict of interest issues and has placed on the chairpersons of its committees,

in consultation with legal counsel, the officers and the board of directors, as needed, the responsibility and capability to do so.

- 1. General Budget Support from Industry.** The general budget of ACMG covers a wide range of activities, including operational costs and annual meetings, research sponsorship, journal publication, and development of practice and laboratory guidelines. Industry funding in support of such activities has been received in the past and managed in such fashion as best to avoid potential or apparent conflict of interest.

ACMG will not ban industry funding, deeming such funding to be essential to the continued operation of the College.

ACMG will accept only unrestricted funding and administer the funds through its central administrative offices.

ACMG will accept an immediate restriction of industry funding to no more than 25% of its operating budget. Industry support will be reviewed annually, and the results presented to the Board of Directors (BOD).

- 2. Annual National Conferences and Periodic Regional Meetings.** ACMG conducts an annual meeting for members and may conduct regional meetings. Industry may contribute to the support of such activities.

A. Industry Sponsorship of Conference Programs

ACMG will abide by the Accreditation Council for Continuing Medical Education (ACCME) Standards for Commercial Support. The ACMG will ensure, through the ACMG Education and Program Committees, that choice of speakers and content of conference programs (including those for which CME credit is offered) remain free of industry influence

B. Conflict of Interest Standards for Program Committee Members

ACMG Education and CME Committee and Program Committee members will adhere to conflict-of-interest guidelines such that selection of topics and speakers will be free of industry influence. All committee members will be required to complete disclosure statements which will be reviewed by ACMG staff and committee chairs prior to appointment to the committee. All disclosure statements will be reviewed at the beginning of committee meetings during introductions of members so that all members of the committee are aware of potential conflicts of interest. This will become a routine part of committee work, and documentation of this disclosure and any discussion will be included in the minutes of the meeting.

The chairperson will ask the committee member to recuse himself/herself from decisions regarding relevant activities of the committee.

C. Gifting of Promotional Items at Meetings

ACMG will not permit company logos to appear on tote bags, lanyards, pens, notebooks and similar items distributed to meeting attendees at registration.

ACMG will permit industry to purchase and occupy booths in the adjoining exhibit hall at conferences. These booths will not be in the obligate path to scientific or educational sessions, to include poster sessions. The area for industry booths will be delineated clearly, so that attendees can choose to enter or avoid the marketing site.

D. Satellite Symposia

ACMG will facilitate industry-sponsored symposia (ISS) to be held outside of the scheduled scientific and educational sessions of an ACMG-sponsored annual meeting or other conference, and will provide limited logistical support for the ISS, for a fee, provided that: (1) ACMG reviews and approves the topic of the ISS and the ISS speakers; (2) The ISS has been approved to offer attendees continuing medical education (CME) credit; (3) All arrangements for approval of CME and any other funding or expenses in connection with the ISS will be the sole responsibility of the industry sponsor of the symposium; and (4) The ISS clarifies, through appropriate statements and disclaimers conspicuously placed at the event, that ACMG has not reviewed and does not approve or endorse the content of the ISS.

ACMG will not facilitate outside events which, while related to an existing exhibition or event, have as their principal purpose, in the view of the ACMG, the desire to benefit from the audience the ACMG attracts." Officers and key leaders of ACMG will not participate in such events.

- 3. Industry Funds for Research by Professional Medical Association (PMA) and PMA Members.** ACMG does not conduct traditional research, although ACMG members may receive funding for research by means of industry-funded grants.

ACMG solely will be responsible for determining research priorities, conducting peer review of potential projects, and deciding which researchers will be supported.

ACMG will not permit industry to provide a grant for a project of its own choosing or to be associated with a specific research project.

ACMG will manage industry research funds from its central administrative offices.

ACMG will control research data and decide when and where data are to be presented or published.

- 4. Industry Funds for Fellowship and Training Programs.** ACMG receives and distributes industry funds for fellowship and training programs.

ACMG will be responsible for all decisions regarding the choice of residents and fellows to receive industry-supported study, training, travel, and research.

ACMG considers it impractical and unnecessary to strike from an award the name of an industry sponsor or to blind the recipient to the source of fellowship or training funds.

ACMG will not compel awardees to meet with industry representatives or acknowledge a company by name in publications or curricula vitae.

ACMG will not permit industry to provide journal subscriptions or books for awardees.

5. Committees that Formulate Practice Guidelines or Outcome Measures.

ACMG has committees that formulate practice and laboratory guidelines and that assess outcome measures. The circumstances of rare disorders may necessitate expert opinion be rendered by academicians who receive support from industry sources.

ACMG will ensure that formulation of guidelines and development of registries/assessment of outcomes are free from industry influence.

A clear process for all committees will be developed for disclosure and management of all potential conflicts of interest. All committee members will be required to complete disclosure statements which will be reviewed by ACMG staff and committee chairs prior to appointment to the committee. Disclosure statements should be reviewed at the beginning of the committee meeting during introductions of members so that all members of the committee are aware of potential conflicts of interest. This will become a routine part of committee work and documentation of this disclosure and any discussion will be included in the minutes of the meeting.

In the instance that formulation of guidelines or assessment of outcome measures requires, because of special knowledge or expertise, the participation in committee activities of members of the College who have ties to industry, the chairperson will ensure, by means of review by other members of the committee or disinterested party external to the committee, that the committee product is free of personal bias or industry influence.

6. Industry Support of Publications. Revenue from industry is acceptable when designated as advertising.

ACMG will continue to solicit and accept advertising revenue from industry for its publications.

ACMG will not accept industry support for publication or distribution of guidelines or advisory material.

ACMG will not display an industry logo on its publications.

ACMG will not accept industry funding for publication supplements, unless such funding is unrestricted and the development of the publication totally under ACMG control.

ACMG publications will not be associated with a commercial brand.

7. Product Endorsements

ACMG will not solicit or accept any offer that would attach its name or logo to any commercial product, service or activity.

8. Affiliated Foundations

At present, the College does not, and in the future, will not receive any funds directly from industry. Such funding will be directed to the ACMG Foundation and disbursed to ACMG as unrestricted funds in accordance with accepted practice and governing regulations.

Standards for the American College of Medical Genetics Foundation (ACMGF) will be identical or similar to those for the College.

9. Conflict of Interest Among PMA Presidents, Officers and Board

Members. ACMG Presidents, Officers and Board Members will be, insofar as is possible, free of conflict of interest while serving as President-elect or Immediate Past-president or as President, Officer or Board Member.

ACMG will require each candidate for membership on the Board of Directors to submit a disclosure statement that will address employment and other sources of income, to include, but not be limited to, honoraria, stipends, consultant fees, and royalties.

Before the name of any candidate is considered for election to the positions of President, Officers, or Members of the Board, the chairperson of the Nominating Committee and the President of the College will review the submitted disclosure statement.

Any statements that contain significant apparent, potential or perceived conflicts of interest then will be forwarded to the Executive Committee of the Board of Directors for additional review and consideration. The Executive Committee will judge the appropriateness of any candidate, in consultation with its legal counsel if desired, and instruct the Nominating Committee as to its findings.

Any individual who is considered to have extant, potential, or perceived conflict of interest may be asked to withdraw his/ her name from consideration for one of the aforementioned positions.

10. Guidance for PMA Members

ACMG encourages its members to emulate the College in their examination of their individual circumstances and in the identification

of and full disclosure, to the College, its Board of Directors, its committees and its members, of any identified or potential conflict of interest or any situation that may be perceived by others to be a conflict of interest. In addition, ACMG expects that its members will be familiar with and adhere to the Conflict of Interest principles and provisions of their respective institutions of employment.

Committee on Conflict of Interest

Mira Irons, MD, FACMG, Chair

Barry H. Thompson, MD, FACMG, ACMG Medical Director/Staff Liaison

Gregory A. Grabowski, MD, FACMG, Member

Wayne W. Grody, MD, PhD, FACMG, Member

R. Rodney Howell, MD, FACMG, Member

David H. Ledbetter, PhD, FACMG, Member

Michael S. Watson, PhD, FACMG, ACMG Executive Director

Melissa T. Forburger, ACMG Director of Administration

Approved by the ACMG Board of Directors October 20, 2009