

The Role of Industry Interactions With the American College of Gastroenterology

ACG Professional Affairs Committee

Am J Gastroenterol 2012;107:800–803; doi:10.1038/ajg.2011.467

The Professional Affairs Committee of the American College of Gastroenterology (ACG) examined the many types of relationships between health industry commercial interests (HICIs) and professional medical associations (PMAs) as they relate to activities of the College and made recommendations to the Board of Trustees. In preparing this report, we consulted with many stakeholders within the College.

HICI–PMA relationships are hotly contested. Critics almost always concede that such relationships can be healthy, useful, and productive, yet such statements most often are a prelude to criticism and recommendations for elimination of most or all of them. There exists a curious disconnect between recommendations made by august organizations (e.g., the Institute of Medicine, the Association of American Medical Colleges, the Macy Foundation) and many providers and consumers of medical education.

There is a paucity of evidence for or against the existence of a pernicious influence of well-regulated HICI support for postgraduate medical education. Cervero and He's 2008 analysis concluded that while there is ample evidence that Continuing Medical Education (CME) affects physicians' prescribing practices, no studies have looked specifically at the impact of prescribing changes on patient outcomes and thus cannot answer the important question of whether observed changes in practice were

or were not in patients' interest. It is necessary to initiate rigorous scientific studies to address important questions about the relationship between commercial support and bias in CME (1).

Since that report was released, studies have been published indicating that HICI-funded educational activities produced under the auspices of current rules and standards of the Accreditation Council for Continuing Medical Education (ACCME) do not have different levels of perceived commercial bias compared with those not funded by HICIs (2,3). Indeed, even activities with a single HICI funding source fare as well in this regard as those without HICI funding.

A recent report by Rothman *et al.* in the *Journal of the American Medical Association* distilled the major issues that PMAs confront as each grapples with its relationship to HICIs (4). It describes seven domains of oversight that each PMA and its affiliated foundations need to oversee: general budget support, PMA meetings, research, fellowship and training, guidelines and outcomes, publications, and product endorsement.

The purpose of this White Paper is to provide a contemporary analysis of practices and procedures that govern College interactions with HICI. It is designed to synthesize in a single document policies adopted by relevant components of the College. The ACG Professional Affairs Committee recognizes the dynamic nature of HICI–PMA relationships, the changing nature of society's expectations, and the highly charged atmosphere in which discussions take place.

Several externally mandated safeguards are already in place that are the result of thoughtful analysis by the ACCME and the American Medical Association, as well as by HICIs, which have developed the Pharmaceutical Research and Manufacturers of America (PhRMA) Code on Interactions With Healthcare Professionals and the Advanced Medical Technology Association (AdvaMed) Code of Ethics (5–7). In the context of weighing the pros and cons of HICI–PMA relationships, this Committee has based its analysis and recommendations on the following tenets:

- HICI–PMA relationships are neither inherently good nor inherently evil.
- Risks implicit in HICI–PMA interactions can be successfully managed.
- HICI and PMA interests may sometimes be coincident.
- Management of conflicts of interest between HICIs and PMAs and their members demonstrably minimizes such conflicts and commercial bias.
- Many standards and codes exist that are substantially successful.
- Transparency to the PMA membership and to all learners regarding HICIs and PMAs is vital.

This report is designed to become a living document, one that can be easily amended or updated as circumstances within society or our College change. It is hoped that

Correspondence: Harris R. Clearfield, MD, MACG, Division of Gastroenterology, Drexel University College of Medicine, 219 N. Broad Street, 5th Floor, Philadelphia, Pennsylvania 19107, USA. E-mail: harris.clearfield@drexelmed.edu

a mechanism can be developed to tag each component so that it can be automatically reviewed and updated by the relevant College entity. If, for example, the *American Journal of Gastroenterology* were to make substantive changes in its HICI policies, these could be reflected in an amended appendix to this document. If the mechanism for achieving this is beyond the perceived value, we recommend that the Board of Trustees make it the statutory responsibility of the Professional Affairs Committee to conduct a formal review and update periodically (for example, at least every three years).

Domains of interactions with industry

There are many domains of potential interaction between the ACG and HICIs. Managing each requires a combination of consistency and sensitivity to the nuanced differences in the potential for undue commercial bias.

1. General budget support from industry.

Operational costs, annual meetings, research, sponsorship, journal publications, and practice guideline development are the major budget items for most PMAs, including the ACG. The ACG embraces general budget support from HICIs and endorses carefully controlled general budgetary support from industry as a means of allowing the ACG to maintain its vibrancy and relevance to its membership. As a matter of sound business principles, the ACG agrees that overreliance on any single source of funding to carry out its mission carries business risk. There frequently is a confluence of interests shared by HICIs and the ACG. Endoscopic equipment, diagnostic testing, and new therapies are of vital interest to the ACG, which represents practicing health-care providers in the field of gastroenterology and hepatology.

Like most not-for-profit organizations, the ACG favors receipt of unrestricted donations that can be pooled and administered through its general budget. The ACG believes that HICI grants for more targeted programs can and should be considered as long as there is complete transparency and genuine value to its membership. The ACG may determine that some potential sources of HICI funding are intrinsically inimical to ACG interests.

2. Annual national conferences and periodic regional meetings. Well-regulated industry support for PMA meetings represents a bona fide example of a healthy confluence of interests of HICIs and the ACG. ACG educational meetings are CME accredited. The ACG has earned the designation "Accreditation with Commendation" from the accrediting body, the ACCME. This accolade is reserved for the top tier of CME providers nationally and certifies, among other things, that the ACG is compliant with all Standards for Commercial Support. These standards ensure that the ACG has strict conflict-of-interest guidelines to avoid HICI influence over content.

The ACG believes that it is appropriate and reasonable to accept HICI funding for educational programs (with either multiple- or single-HICI funding). Complete editorial control by the ACG and transparency to the learner represent a robust management strategy. The ACG provides a number of abstract awards for high-quality science submitted to the ACG Annual Meeting. Some of these awards are funded directly by the ACG, and some are HICI funded and publicly recognized as a joint award with the ACG. Regardless of whether the awards are funded directly by the ACG or have outside funding, the ACG maintains complete independence and control over the award criteria and selection process in all cases.

The ACG supports the continuation of a well-managed series of HICI-funded satellite symposia and prefers that such meetings grant CME and be conducted in compliance with ACCME Standards for Commercial Support. Consistent with abundant published data indicating no perception of greater commercial bias in CME-accredited programs with a single funding source, the ACG believes that such programs are a vital and important service to its members. The ACG does not support providing member information to HICI sources. However, it does endorse providing reasonable information to CME-accredited providers responsible for the organization of satellite meetings.

The ACG ensures that the spaces in which educational activities of the College are held, including committee meetings and education programs, do not simultaneously serve any commercial purpose. The conduct of HICIs in spaces allocated and reserved for their use, such as the exhibit hall, is guided by business ethics, including the updated PhRMA Code on Interactions With Healthcare Professionals and the AdvaMed Code of Ethics.

The location of HICI commercial booths is often dictated by the geography of the meeting facility. The ACG adheres to the ACCME Standards for Commercial Support, which call for a physical separation of commerce and CME sessions. The ACG has standards for commercial exhibits at its meetings. These do not specify a ban on food distribution within the commercial space. The ACG leadership believes that such a ban is inappropriate because the exhibits take place in commercial exhibit space that is advertised as such to all who enter.

The ACG ensures that fees charged for commercial space are a separate and distinct transaction from an HICI unrestricted educational grant. There are no *quid pro quos*. All HICI purchasers of commercial space are treated equally without regard to whether that HICI has provided an educational grant.

3. Industry funds for research by PMAs and members. The ACG Institute for Clinical Research and Education funds many research projects. The ACG and the ACG Institute have procedures in place to ensure that HICA grants are for projects of benefit to our members. The ACG and the ACG Institute believe that there is an ethical obligation to reveal information about the origins of research funding, a situation precisely analogous to the requirement embedded in ACCME Standards for Commercial Support for educational activities. The ACG and the ACG Institute do not allow HICIs to provide grant support for projects of their choosing. HICI research grants go to a central repository, and all research-grant requests from ACG members are peer reviewed without HICI involvement. The ACG, ACG Institute, and research-grant awardees control the data and the timing and mode of presentation.

4. Industry funds for fellowship and training programs. From time to time, HICIs provide funding for the ACG to support training grants. The ACG adheres to the following principles related to these programs:

- The ACG is solely responsible for the selection of trainees.
- Award of a commercially funded training grant does not obligate the grant recipient to meet with representatives from HICIs, nor does it prohibit the grant recipient from doing so.
- The HICI source for the training grant is acknowledged as a matter of transparency.
- The ACG does not permit direct HICA provision of items of value such as books, journal subscriptions, and travel support to training-grant recipients.

5. Committees that formulate practice guidelines or outcome measures. PMA-produced documents are influential in many ways and often guide decision making by practitioners. They may influence recommendations for purchase of commercial goods and services. PMA documents also influence governmental and insurance purchasing decisions. PMAs therefore have a special obligation to inform their documents with scientifically valid information and complete freedom from commercial influence. Accordingly, the ACG does not accept HICI funding for any aspect of the development or dissemination of practice guidelines.

Those who write practice guidelines and the committees that oversee them have a special responsibility. This subject was recently reviewed (8). Some have argued that only those with no ties to industry should be allowed to serve on such committees. The ACG agrees that prohibiting people with any industry ties from participating in the creation of guidelines would be preferable if a pool of highly knowledgeable people with no industry ties were available. Pragmatically, this is usually not the case in clinical gastroenterology. The Practice Parameters

Committee, therefore, has created a policy that requires an explicit review for potential conflict of interest for all those participating in guideline generation. This review may result in recusal of one or more authors or the specific recommendation of actions such as divestment of interests before participation in the process (1).

6. Industry support of PMA publications. The impact of PMA publications is significant. There is considerable intersection of interest of HICA and publications from PMAs. The ACG and its journals are highly sensitive to the potential for undue commercial influence in its publications. The ACG journals adhere to the following principles:

- ACG journals do not permit the presence of an HICI logo on the cover or on an internal page that has the appearance of representing the journal (table of contents, instructions to authors, etc.).
- ACG journals have firewalls between advertising and scientific and editorial content. Editorial decisions are made independently and are never tied, for example, to the possibility of generating advertising revenue. Advertising placement based on journal content is prohibited.
- Reprints purchased in bulk by HICIs cannot bear corporate or product logos.

7. Product endorsements. The ACG does not permit product endorsements and does not solicit or accept any offer that would attach its name or logo to a commercial product, service, or activity.

8. Affiliated foundations. The close alignment of the ACG and the ACG Institute makes them largely indistinguishable in the minds of our membership and the public. The ACG Institute is held to the same standards as the parent organization.

9. Conflicts of interest among PMA presidents, officers, and board members. The reputation of the ACG is heavily dependent on the integrity and reputation of the leadership.

The ACG has mechanisms in place to ensure compliance with the following:

- Potential conflicts of interest among ACG presidents, officers, and board members must be avoided or managed to the highest standards.
- ACG policy requires board members to disclose all potential or actual conflicts and to not participate when any activity bearing on their conflict arises.
- ACG executive and administrative staff should have no financial ties with industry.
- ACG executive and administrative staff are prohibited from accepting gifts or other favors.
- HICIs are not permitted to fund any board activity.
- The ACG has a formal mechanism for reviewing conflict of interest.
- Disclosure forms are detailed and explicit, requiring descriptions of activities and the sums received so that appropriate decisions can be made about recusal or removal of any individual.

Whether or not high officials of PMAs (the president, officers, and board of trustees) must divest themselves of all commercial ties has been a matter of much debate nationally. The ACG has been at the forefront of developing mechanisms to explore the best management strategy to ensure that its integrity is maintained. The ACG agrees that all activities of the Board of Trustees must be taken without conflicts of interest. The ACG does not agree with the recommendations that elimination of all association with industry is the only path to effective management of conflict of interest. Taking into account the long duration on the leadership ladder, it is an unrealistic demand. The ACG, instead, provides alternative ways of managing potential conflicts of interest through its Conflict of Interest Committee, made up of senior College members (mostly past presidents). The ACG requires officers of the

College to make transparent all commercial ties and to recuse themselves from deliberation on pending college business where a conflict of interest may be present.

Internal vigilance and benchmarking

Recent reports identify some disconnects between written policies and procedures and their effectiveness among societies (9) as well as medical publications (10). These observations indicate that at the intersection of individual and PMA responsibility lies a vulnerability that may require added vigilance.

The Committee interprets this and similar data as indicating that the oversight role required by PMAs and their agents is a never-ending one. Every PMA needs transparent policies and procedures to reduce HICI-induced bias within its operations, but it also needs an independent auditing function to ensure that its policies are effective. A periodic independent audit might be one vehicle to ensure the effectiveness of PMA policies and procedures. The Committee recommends that the Board of Trustees develop mechanisms of regular reviews of each relevant component of the College (journals, Institute, Practice Parameters Committee, Conflict of Interest Committee) to ensure that its conflict-of-interest policies and procedures are accomplishing their intent.

Summary and conclusions

Society has an interest in the conduct of professional medical associations, particularly as it relates to their interactions with industry. Intense scrutiny is likely to continue and will probably increase. The American College of Gastroenterology has been at the forefront of awareness of the critical intersection of our interests and those of industry and has been proactive in the development of appropriate policies and procedures to manage the risk of conflict of interest and of infiltration of commercial bias into its work products.

The College must continue to be vigilant and to recognize that human frailty will always be present and will test the limits of existing policies and procedures. The corollary need for repeated review and revision seems incorporated into the DNA of College leadership.

CONFLICT OF INTEREST

The Professional Affairs Committee collectively participated in the preparation of this White Paper and reviewed and approved the final draft. There were no potential financial or other conflicts of interest, and the Committee received no editorial assistance in its preparation. No Committee member had any relationship entailing financial or editorial support.

REFERENCES

1. Cervero RM, He J. The relationship between commercial support and bias in continuing medical education activities: a review of the literature. Accreditation Council for Continuing Medical Education <http://www.accme.org/sites/default/files/null/2008_06_Cevero%20final%20report_The%20Relationship%20between%20Commercial%20Support%20and%20Bias%20in%20Continuing%20Medical%20Education%20Activities_A%20Review%20of%20the%20Literature.pdf> (2008).
2. Kawczak S, Carey WD, Lopez R *et al*. The effect of industry support on participants' perception of bias in continuing medical education. *Acad Med* 2010;85:80–4.
3. Steinman MA, Boscardin CK, Aguayo L *et al*. Commercial influence and learner-perceived bias in continuing medical education. *Acad Med* 2010;85:74–9.
4. Rothman DJ, McDonald WJ, Berkowitz CD *et al*. Professional medical associations and their relationships with industry. *JAMA* 2009;301:1367–72.
5. Accreditation Council for Continuing Medical Education. Standards for Commercial Support <<http://www.accme.org/requirements>>.
6. Pharmaceutical Research and Manufacturers of America. Code on Interactions With Healthcare Professionals <http://www.phrma.org/sites/default/files/108/phrma_marketing_code_2008.pdf>.
7. Advanced Medical Technology Association. Code of Ethics <<http://www.advamed.org/MemberPortal/about/code>>.
8. Okike K, Kocher MS, Wei EX *et al*. Accuracy of conflict-of-interest disclosures reported by physicians. *N Engl J Med* 2009;361:1466–74.
9. Chimonas S, Frosch Z, Rothman DJ. From disclosure to transparency: the use of company payment data. *Arch Intern Med* 2011;171:81–6.
10. Guyatt G, Akl EA, Hirsh J *et al*. The vexing problem of guidelines and conflict of interest: a potential solution. *Ann Intern Med* 2010;152:738–41.