

Consulting Management Committee  
UCHC Request for Action #9 – Promotional Activities & Material Roles in Developing the  
Content, Curriculum and/or Materials for an Educational Activity

**Date:** September 18, 2008

**Submitted by:** Scott Wetstone, Director of the UCHC Faculty Consulting Office

**Description of Issue**

A faculty member has been asked to participate in what he characterized as “promotional” presentations. These are presentations designed to sell a contracting entity’s product and/or service. Unlike traditional academic/scientific presentations, promotion presentations are characterized by the lack of a balanced presentation of the strengths and weaknesses of all other potential products and services, and/or, the content of the presentation being substantially controlled by the contracting entity.

In the situation cited above, the faculty member’s presentation would include the discussion of a legitimate clinical problem, its epidemiology and its pathophysiology. The audience would be physicians. These presentations would be made during an expensive dinner and would only be 15 minutes in length. Compensation would be \$2,000 per presentation and the faculty member would make many presentations over year.

In contrast to this request is a subsequent request received a week later from a different faculty member. This new activity was described as promoting the use of a therapeutic modality in front of regulators and the compensation level is high. In this case, however, the faculty member is literally the “founding father” of the therapeutic modality and is recognized internationally as the pre-eminent authority on it. In addition, UCHC has licensed the modality to the commercial entity and the faculty member has an equity interest in the company but less than 5%. Lastly, the presentations are limited to only discussions of the peer-reviewed work previously published by the faculty member.

It is unclear whether other faculty have been engaging in promotional presentations but have been referring to them by other names such as “dinner presentation”, “presentation to a physician group”, “discussion group leader” or simply “presentation”. By default, these have been treated as traditional academic/research presentations.

My questions related to the faculty’s role in participating in promotional activities are:

- 1) What is the definition of “promotional presentations”?
- 2) Under what, if any, circumstances should such requests be denied?
- 3) What additional procedures, if any, should be implemented in order to identify promotional presentations from more traditional academic/scientific presentations?

## Previous Opinion(s) of the Office of State Ethics

A previous written opinion of a staff attorney concluded that anyone who writes prescriptions is essentially a purchasing agent. This opinion banned any consulting for a contracting entity that provides a product or services that the faculty member writes a prescription for or its competitors. This was one of the OSE opinions that motivated the University to seek the carve out legislation.

## Discussion

The first case described above describes a situation under intense national scrutiny, that being, commercial entities inappropriately influencing physician prescribing practices. Such presentations are not eligible for Category 1 AMA CME credit hours due to the lack of a balanced presentation of other treatment options. CME rules would also require the faculty member have the freedom to design the talk without the involvement of the contracting entity, although in the first situation described above, it is unclear whether this is the case or not.

Many professional groups are currently developing and releasing policies regarding the acceptance of funds from such contracting entities. A policy is under development at UCHC regarding this, but not yet approved. Many would characterize the receipt of such monies for promotional presentations, as presented in the first case, as being unprofessional.

Such presentations would not be allowed under the Code of Ethics as interpreted by the OSE if the faculty member writes prescriptions for a product or service provided by a contracting entity or its competitors. The definition of consulting used in State statutes that enabled the carve out and in the University's Consulting policy requires the faculty member to be personally compensated for services rendered while not acting as a State employee and when s/he was asked to consult based on his/her professional expertise and/or prominence in his/her field. In all likelihood, commercial entities choose speakers for promotional activities due to their prominence in their field if not also their professional expertise.

In the University's policy on consulting, one requirement for approval of requests to consult is that it contributes to the faculty's member's faculty development. It might be argued that the opportunity to speak in front of an audience, especially of other professionals, enhances the faculty member's ability to teach. It might also be argued that it helps build a local, regional and/or national reputation which is an important criterion for promotion.

It is also possible to argue that participation in such activities is harmful to the development of a faculty member. In essence, it is unprofessional behavior and/or tarnishes one's reputation. The Bylaws of the University require that faculty demonstrate "Personal attributes; **integrity**, industry, **open-mindedness**, **objectivity**, friendliness, effectiveness in speaking, capacity for leadership and cooperation, breadth of intellectual interests." (Article XV., my emphasis.)

### **Addition Discussion – 7/23/10, 11/5/10, and 12/10/10.**

Over the last year, the UCHC Faculty Consulting Office has become aware of circumstances in which faculty have been asked to provide educational sessions in which they have control of the educational content, but do not have complete control of the use of educational materials (primarily slides) during such sessions. In some cases the faculty member could only use slides from a pre-certified deck of slides (in whole or in part) but could change the order of slides chosen. In some cases the faculty member could ask to modify such slides or even create his/her own new slides, but such slides might be limited in number or must have been approved by the contracting entity. The contracting entity could require that all educational materials used in an educational session carry the name or logo of the contracting entity or another third party.

It remains imperative that educational activities delivered by our faculty be under the control of the faculty member both in terms of content and education materials used. The academic reputations of the faculty are based on this premise. In the least, use of pre-certified slides and/or slides with the name of the contracting entity or another third party gives the appearance that the presentation is not under the control of the faculty member and that a conflict of interest might exist. Selective and non-material use of educational materials developed by others is permissible so long as such use is not required by the contracting entity.

The issues described above are not limited to presentations but to any educational activity including group discussions, panel discussions, demonstrations and similar activities.

### **Additional Discussion – July 2011 (email meeting), October 7, 2011, January 13, 2012, and January 31, 2012 (email meeting).**

A faculty member was requested to present a journal club with a pharmaceutical company as the contracting entity. The choice of article(s) to be reviewed would be chosen by the faculty member from a limited list of acceptable articles established by the contracting entity.

The choice of articles used in a journal club, or cases in a case discussion, can drive the nature of the discussion during an educational session. Therefore, the faculty member should have unrestricted choice regarding the journal or cases to be used. A general topic area is not considered as being overly restrictive and is acceptable.

Sometimes, the pharmaceutical company's 'contract' with the faculty member (whether that be a formal document or a less formal communications), requires the use of specific language or slide(s) that have been approved and/or are required by the Food and Drug Administration or similar agency. Such requirements are usually if not always is an indication that the pharmaceutical company believes the educational presentation will be considered a promotional presentation by the government. This is also a warning sign to us that the presentation is promotional.

Previously, the Consulting Management Committee has determined that a faculty member may not be paid by a commercial entity to attend training in how to be a better speaker for that entity (i.e. to be a better presenter for that entity's "speaker's bureau". The Committee believed that such activities do not add to the professional development of the faculty member which is a requirement of all consulting activities.

In addition to this concern, it seems evident that being trained by such an entity to be a better speaker is intended to make them better able to promote either the specific products of the company and/or general therapeutic approaches that would likely benefit that entity. In the least, this has a perception of a conflict of interest (i.e. why would a commercial entity invest resources in training faculty to speak better?). Therefore, the restriction on being paid to be trained to be a better speaker should also be articulated in this CMC decision on promotional presentations.

In the event that a sponsoring organization is for-profit, the organization's name and/or logo can only appear in the presentation for the purposes of acknowledgment at the beginning and/or end, of the presentation but not throughout the presentation. When the sponsoring organization is a non-profit entity, the name and/or logo may appear throughout the presentation.

### **Recommendations:**

- 1) The CMC should adopt a definition of promotional activities that includes the following concepts:
  - a. Are intended to promote a product or service and do not allow for a fair and balanced presentation of alternative products and services, OR
  - b. When a commercial contracting entity develops a significant proportion of the content and/or materials (e.g. handouts, slides, etc) used by the faculty member in such activity, OR
  - c. When the name of the contracting entity or another third party is placed on such materials,<sup>1</sup>
  - d. An exception to this definition is when the faculty member is only presenting on his/her own peer-reviewed published works.
- 2) A set of questions should be developed to help identify promotional activities. These questions would be used at the discretion of the Director of the Faculty Consulting Office, but always when the contracting entity is a commercial firm and the activity is a speaking engagement. Such questions would include:
  - a. Will the activity include discussion of a product or service? (If no, skip to question 'g'). If yes, answer all the questions below.)
  - b. Will there be a fair and balanced presentation of alternative products and services? Some indications of balance include, but are not limited to, open-

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<sup>1</sup> Exceptions: a) The name and/or logo of the contracting entity can be displayed at the beginning and/or the end of the presentations/educational materials but only as part of an acknowledgement that the faculty member was paid by that entity, and b) The name and/or logo of the contracting entity may be on any number of slides as part of a master slide (i.e. "template") so long as that entity is a nonprofit professional society, nonprofit academic institution, or governmental agency.

ended case discussions, the discussion of all peer-reviewed articles in which a head to head comparison of products and services were made.

- c. Are continuing credit education credits being offered to the audience for this activity? If yes, what type of credits are being offered?
  - d. How long is the actual activity?
  - e. Who is the target audience and how are they recruited?
  - f. Will the contracting entity be providing expensive meal(s) or providing other financial gifts (including travel expenses) to the participants?
  - g. Will the contracting entity play a material role in developing the content of your educational activity or materials supporting your presentation? Describe the level of control you have in developing the content and materials to be used in the activity and similarly the role the contracting entity or others will play in developing the content and materials to be used including but not limited to the handouts, slides, and/or the selections of journal articles or case reports to be used.
  - h. Will the educational materials used have the name or logo of the contracting entity or another third party on them? If yes, in what ways?
  - i. Does the contracting entity require the use of any specific language in your presentation (such as FDA or other government approved verbiage) and/or specifically restrict any specific language and/or topics from presentation and discussion?
- 3) The CMC should ban future approval of consulting that includes promotional activities, educational activities in which the faculty members does not have material control over the content of the educational materials, or educational activities in which the educational materials bear the name and logo of the contracting entity or other 3<sup>rd</sup> party<sup>1</sup>. The occasional use of slides and/or figures created by the contracting entity or other 3<sup>rd</sup> party is permissible when they address issues of science and not products or services and in such cases, the source of the slide/figure may be indicated on it.

For activities in calendar year 2010 and 2011, any faculty member whose request to consult is denied because it is deemed a promotional activity or because the faculty member was not deemed to have sufficient control of the content or educational materials used in such activity, has the right to appeal that decision to the Consulting Management Committee. Such an appeal must be made in writing within two weeks of the decision to deny the request. This initial appeals document should completely lay out the faculty member's issues and all supporting documentation.

The chairs of the CMC will decide whether such an appeal will be resolved through an email or face to face meeting of the CMC as well as whether the faculty member will have an opportunity to participate in the discussion of his/her case directly (i.e. to meet with the Committee or be part of an email discussion.). The Director of the Faculty Consulting Office will provide the Committee the faculty member's responses to the

questions listed in 2a-2g above and the director's responses to the issues raised in the initial appeal document.

If the appeal is successful, the Director of Faculty Consulting will so notify the faculty member immediately. If and until such time, the faculty member may not participate in the requested activity.

- 4) The CMC should ban consulting in which faculty are being paid to become better speakers when the contracting entity is a commercial entity or working for a commercial entity

### **CMC Response**

On September 18, 2008, the Consulting Management Committee unanimously approved the recommendations as written above. On December 12, 2008, the Consulting Management Committee revised recommendations 2 - 3. On December 10, 2010 the Consulting Management Committee added "Additional Discussion- 7/23/10, 11/5/10, and 12/10/10" to this decision and revised recommendations 1-3 accordingly. On January 31, 2012, the Consulting Management Committee added "Additional Discussion – July 2011 (email meeting), October 7, 2011, January 13, 2012, and January 26, 2012 (email meeting)" to this decision, revised recommendation 2, and added recommendation 4 accordingly.