

ESSENTIAL AREA 3 (ADMINISTRATION)

Disclosure and Commercial Support Standards (Element 3.3)

The Office of CME at Johns Hopkins School of Medicine presents its activities in full compliance with the ACCME Essential Areas and policies on commercial support, including financial disclosure, disclosure of information relating to investigational products or products not labeled for use, the use of trade names in a promotional manner during presentations, the management of funds obtained from commercial sources and the management of exhibits at educational activities.

Commercial Relationships of the Faculty

OCME has a Policy on Disclosure that requires faculty to be notified of applicable commercial support policies, and requires that conference coordinators prepare and mail a faculty letter. The latter document specifies commercial support requirements and includes a standardized Faculty Disclosure Form to enable faculty to make appropriate financial disclosure relative to their relationships with the supporter of an activity and manufacturers of any product discussed in the CME activity. The format also collects information on a faculty members intention to discuss unlabeled or unapproved uses in their presentations. The Disclosure Form also contains clearly enumerated requirements for faculty behavior relating to the commercial support policy. Faculty are asked to sign the form indicating that they have read the policy and agree to abide by it.

Based on the information obtained from the Faculty Disclosure Form, disclosure is provided to the audience in writing – typically in the activity's course materials. In the rare event that course materials were not able to include disclosure information for logistical reasons, this notification is made verbally from the podium by the course director and is documented in writing for the files.

Attached to this section are (1) OCME's Policy on Disclosure, (2) the Faculty Disclosure Form and Faculty Agreement, and (3) and an example of actual disclosure made at a CME activity sponsored by OCME.

Disclosure of Unlabeled/Unapproved Uses

Beginning in 1999, OCME began to include Disclosure of Unlabeled/Unapproved Uses in course materials. However it was not universally implemented until January 2000. After the 1998 AMA Conference on Industry/FDA Relations in Washington, DC, based on the events leading up to the Pedicle Screw Case, OCME began to expand its policies on disclosure and instruct staff to enforce this requirement. In addition, notices were included in course materials to this effect. However, an analysis

of this practice indicated that the notification to the attendee regarding investigational product discussions in CME activities was not meaningful enough. In late 2000, stronger reminders were in place with faculty, and the course directors and staff specifically asked faculty to make verbal disclosures in live activities when such uses were discussed. Furthermore, enduring materials, including Internet CME activities, were targeted for additional scrutiny by OCME management. Finally, OCME enhanced its existing Course Director's Evaluation form so that the course director could document that such disclosure was made by faculty.

Attachments to this section include (1) an example of an unlabeled or unapproved use disclosure made at a recent CME activity, and (2) a sample Course Director's Evaluation Form.

Other Commercial Support Practices

- Letters of Agreement

OCME policy requires the use of a standardized commercial support Letter of Agreement (LOA). OCME has two versions of the LOA: a two party agreement for directly-sponsored activities and a three-party agreement for jointly-sponsored activities.

- Acknowledgment of Commercial Support

OCME policy requires that all promotional materials and course materials formally acknowledge the receipt of an unrestricted educational grant by a commercial supporter. This is a routine procedure for all activities.

- Separation of Promotion and Education

OCME carefully selects partners it works with based on their past performance and adherence to ACCME Essential Areas and policies. When exhibits are offered at educational activities, OCME policy requires that they be placed in a separate space from the room housing the educational activity, and that they not be in the obligate pathway leading to the educational activity. No product promotion whatsoever is permitted in educational rooms. Representatives are supervised by staff to assure that no promotion is taking place in the meeting room. Occasionally, a commercial supporter is requested by OCME to assist with the promotion of an activity that they have supported. Such requests are made in writing by OCME and the commercial entity is advised of rules for promotional assistance regarding product promotion concomitantly with the promotion of the activity.

- Control Over Content

The planning and design of all CME activities sponsored or jointly-sponsored by OCME are under the direction of the planning committee, headed by the course director and in concert with the OCME conference coordinator. The course director and/or educational reviewer of all activities sponsored or jointly-sponsored by OCME must be a full-time member of the Medical School faculty. Activity planning process is overseen by the Director including a review of activity learning objectives developed by planning committees.

- Management of Funds

OCME directly manages funds for all directly-sponsored activities. Those funds are made payable to the Johns Hopkins University and are directly-managed by OCME conference coordinators. For jointly-sponsored activities, OCME sometimes elects to have the joint sponsor manage the funds under the direction and with the approval of the Office of CME. This arrangement is managed in the following ways:

- OCME initiates a Joint Sponsorship Agreement that stipulates fund management responsibilities and the role of the OCME to review and approve all budgets
- OCME prepares a three-way commercial support Letter of Agreement that delineates the roles of the sponsor, the joint sponsor and the commercial supporter. In that document, the joint sponsor is designated to receive commercial support funds under the direction of the OCME
- OCME reviews honoraria for faculty and assures that amounts paid to faculty are reasonable and within national norms
- The joint sponsor is required to submit a final reconciled report on the distribution of funds to OCME and must adhere to the pre-approved budget
- Changes in budgets must be approved in advance by OCME

Copies of the standardized letters of agreement, the Policy on Joint Sponsorship, an index from our website indicating forms and procedures available to joint sponsors and other partners, and the Policy on Commercial Support are attached to this section.

- Social Events at CME Activities

Although all CME social events have been consistent with ACCME and AMA Standards and Guidelines, no written and approved CME policy had been previously established. The CME Advisory Board has now developed a strict policy on limited social events that are permissible at CME activities sponsored by Johns Hopkins University School of Medicine. This new policy and its companion check list were adopted by the CME Advisory Board and distributed to all staff and joint sponsors. Today, any social event must be pre-approved in writing by the Associate Dean and Director and follows all AMA and ACCME guidelines. A copy of that policy and checklist are attached.

JOHNS HOPKINS UNIVERSITY SCHOOL OF MEDICINE

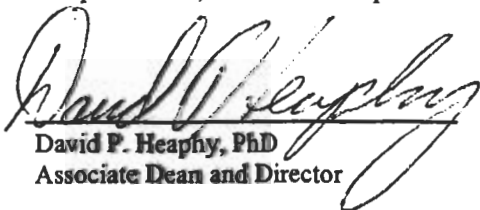
POLICY ON COMMERCIAL SUPPORT

In accordance with the *Standards for Commercial Support of Continuing Medical Education* of the Accreditation Council for Continuing Medical Education (ACCME), Johns Hopkins University School of Medicine adopts the following policy:

- 1) Johns Hopkins University School of Medicine fully supports and adopts the ACCME *Standards for Commercial Support of Continuing Medical Education* as its basis for relating to commercial support companies with regard to CME.
- 2) CME activities sponsored by Johns Hopkins University School of Medicine must use the Johns Hopkins University School of Medicine -approved Letter of Agreement for all CME activities. The CME Director must be directly involved in the contractual process between Johns Hopkins University School of Medicine and the commercial support company.
- 3) All continuing medical education activities sponsored by Johns Hopkins University School of Medicine shall ensure that in-depth presentations are independent, balanced, objective and scientifically rigorous.
- 4) Johns Hopkins University School of Medicine is solely responsible for the administration, content, quality and integrity of all continuing medical education activities.
- 5) In accordance with ACCME Essential Areas and policies, Johns Hopkins University School of Medicine must be totally responsible for all decisions on key components of activity development, including the development of activity goals and objectives, promotional material, text content, faculty approval and guidance, activity evaluation, and issuance of certificates.
- 6) Johns Hopkins University School of Medicine is solely responsible for the quality, content and utilization of instructional materials or post-activity documents that are prepared with the support of outside organizations.
- 7) Activities which provide information in whole or in part related to non-FDA approved uses for drug products and/or devices must disclose when an unlabeled use of a commercial product, or an investigational use not yet approved for any purpose is discussed. Faculty are required to disclose to the audience that the product is not labeled for the use under discussion or that the product is still investigational.
- 8) Acknowledgment will be made of any outside organization providing financial support for any component of an educational activity.

Approved: CME Advisory Board, February 27, 2001

Adopted: Dean, The Johns Hopkins University School of Medicine, March 12, 2001



David P. Heaphy, PhD
Associate Dean and Director

LETTER OF AGREEMENT
for ACCME and State Medical Society Accredited CME Sponsors
Regarding Terms, Conditions and Purposes of an Educational Grant

Between **Johns Hopkins University School of Medicine** and _____

Title of CME Activity: _____

Location: _____ Date(s): _____

Commercial Supporter (Company Name/Branch): _____

Address: _____

Telephone: _____ Fax: _____ Contact Person: _____

The above company wishes to provide support for the named continuing medical education activity by means of an unrestricted educational grant for support of the CME activity in the amount of \$ _____.

1. **Statement of Purpose:** Program is for scientific and educational purposes only and will not promote the company's products, directly or indirectly.
2. **Control of Content & Selection of Presenters & Moderators:** Sponsor is responsible for control of content and selection of presenters and moderators. The Company agrees not to direct the content of the program. The Company, or its agents, will respond only to Sponsor-initiated requests for suggestions of presenters or sources of possible presenters. The Company will suggest more than one name (if possible); will provide speaker qualifications; will disclose financial or other relationships between Company and speaker, and will provide this information in writing. Sponsor will record role of Company, or its agents, in suggesting presenter(s); will seek suggestions from other sources, and will make selection of presenter(s) based on balance and independence.
3. **Disclosure of Financial Relationships:** Sponsor will ensure meaningful disclosure to the audience, at the time of the program, of (a) Company funding and (b) any significant relationship between the Sponsor and the Company (e.g., grant recipient) or between individual speakers or moderators and the Company.
4. **Involvement in Content:** There will be no "scripting," emphasis, or direction of content by the Company or its agents.
5. **Ancillary Promotional Activities:** No promotional activities will be permitted in the same room or obligate path as the educational activity. No product advertisements will be permitted in the program room.
6. **Objectivity & Balance:** Sponsor will make every effort to ensure that data regarding the company's products (or competing products) are objectively selected and presented, with favorable and unfavorable information and balanced discussion of prevailing information on the product(s) and/or alternative treatments.
7. **Limitations on Data:** Sponsor will ensure, to the extent possible, meaningful disclosure of limitations on data, e.g., ongoing research, interim analyses, preliminary data, or unsupported opinion.
8. **Discussion of Unapproved Uses:** Sponsor will require that presenters disclose when a product is not approved in the United States for the use under discussion.
9. **Opportunities for Debate:** Sponsor will ensure meaningful opportunities for questioning or scientific debate.
10. **Independence of Sponsor in the use of Contributed Funds:**
 - a. funds should be in the form of an educational grant made payable to Hopkins/_____
 - b. all other support associated with this CME activity (e.g., distributing brochures, preparing slides, etc.) must be given with the full knowledge and approval of Johns Hopkins University School of Medicine.
 - c. no other funds from the commercial company will be paid to the program director, faculty, or others involved with the CME activity (additional honoraria, extra social events, etc.).

The Commercial Supporter agrees to abide by all requirements of the ACCME *Standards for Commercial Support of Continuing Medical Education*.

The Accredited Sponsor agrees to: 1) abide by the ACCME *Standards for Commercial Support of Continuing Medical Education*; 2) acknowledge educational support from the commercial company in program brochures, syllabi, and other program materials, and 3) upon request, furnish the commercial supporter a report concerning the expenditure of the funds provided.

AGREED

Commercial Company Representative: _____

Signature: _____ Date: _____

CME Department Director or Designee: _____

Signature: _____ Date: _____

Company Representative
Company Address

Dear (Company Representative):

On behalf of the Johns Hopkins University School of Medicine, we would like to enlist your assistance in distributing program invitations to the educational program, (title of the program), which will be on (date) (during the AAPA's annual conference).

It is understood that company assistance will be provided as an educational service to the medical profession and in no way will the company's personnel utilize contacts with physicians being made on behalf of this Johns Hopkins program as a promotional opportunity for company. Please indicate your acceptance and approval of this agreement on behalf of (company name) by returning a copy of this letter with your signature in the space provided below.

We would like to thank you for your assistance in this matter and look forward to a very successful educational program.

Sincerely,

Victor Marrow, Ph.D.
Executive Director
Office of Funded Programs
Continuing Medical Education

Company Representative

Date

JOHNS HOPKINS UNIVERSITY SCHOOL OF MEDICINE

POLICY ON DISCLOSURE

1. **Faculty and Sponsor Relationships**

In keeping with the requirements of Essential Areas and policies relating to commercial support of the Accreditation Council for Continuing Medical Education (ACCME) and in an ongoing effort to provide physicians participating in CME programs with activities, products and services which are objective and scientifically rigorous, Johns Hopkins University School of Medicine has developed the following policy on disclosure of significant financial relationships or other relationships a faculty member or sponsor has with the manufacturer, distributor or marketer of any commercial product discussed in an educational presentation.

This policy requires disclosure of any affiliations between a presenter and any organization that may have a direct interest or financial involvement in the educational activity, product or service provided by Johns Hopkins University School of Medicine. In addition, faculty are required to disclose any financial relationships they may have with the manufacturer of any product or class of products they plan to discuss in an educational activity provided by Johns Hopkins University School of Medicine.

This policy is designed to provide the target audience with an opportunity to review any affiliations between faculty and supporting organizations for the purpose of determining the potential presence of bias or influence over educational content. This policy is not intended to prevent a faculty member with such an affiliation or relationship from participating in the development or delivery of the educational activity.

2. **Discussion of Unlabeled/Unapproved Uses**

Activities formally designated as certified for AMA/PRA category 1 credit by an organization accredited by the ACCME may allow faculty to discuss unlabeled or unapproved uses of drugs or medical devices.

When this occurs, however, the audience must be advised so that they may take this information into consideration in making a determination as to whether or not to implement the information they learned into their medical practices.

Therefore, Johns Hopkins University School of Medicine requires presenters at its activities certified for credit to make this disclosure to the audience in a *meaningful* way. In activities in which there will be such discussion, syllabus materials for CME activities will contain a general statement that discussion of unlabeled or unapproved uses of drugs or devices will take place. In addition, presenters will be asked whether or not they will be having those discussions in their Faculty Disclosure Statement, and this information will be provided to the activity's course director. Faculty will be advised to disclose this information to the audience when such discussions occur.

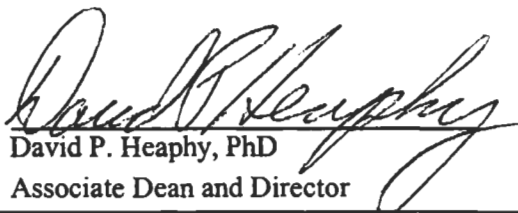
3. Implementation of the Policy

1. Faculty will be requested to complete Johns Hopkins University School of Medicine's Faculty Disclosure Form, which shall contain the following information and request the following disclosure:
 1. The form shall note the title of the activity and the name(s) of commercial supporters associated with the activity;
 2. The form shall solicit information about financial relationships the faculty member or his/her family have with any commercial supporter associated with the activity; if none, there shall be a check box to that effect;
 3. The form shall request information about whether or not the faculty member will be discussing therapeutic options related to manufacturers of other products or devices in his/her presentation. If the answer to that question is yes, the form shall request information about any financial relationships the faculty member or his/her spouse/dependant children have with those manufacturers;
 4. The form shall inquire as to whether or not the faculty member intends to discuss unlabeled or unapproved uses of drugs or devices in his/presentation;
 5. The form shall summarize other pertinent requirements as stated in the ACCME Essential Areas and policies with regard to commercial support.

4. Approvals

Approved: CME Advisory Board, February 27, 2001

Adopted: Dean, The Johns Hopkins University School of Medicine, March 12, 2001



David P. Heaphy, PhD
Associate Dean and Director

THE JOHNS HOPKINS UNIVERSITY FACULTY DISCLOSURE FORM

As a sponsor accredited by the Accreditation Council for Continuing Medical Education (ACCME), The Johns Hopkins University Office of CME must ensure balance, independence, objectivity, and scientific rigor in all its individually sponsored or jointly sponsored educational activities. All faculty participating in a sponsored activity are expected to disclose to the activity audience any significant financial interest or other relationship (1) with the manufacturer(s) of any commercial product(s) and/or provider(s) of commercial services discussed in an educational presentation and (2) with any commercial supporters of the activity. (Significant financial interest or other relationship can include such things as grants or research support, employee, consultant, major stockholder, member of speaker's bureau, etc.). The intent of this disclosure is not to prevent a presenter with a significant financial or other relationship from making a presentation, but rather to provide listeners with information on which they can make their own judgments. It remains for the audience to determine whether the presenter's interests or relationships may influence the presentation. In addition, presenters must make a meaningful disclosure to the audience of their discussions of unlabeled or unapproved drugs or devices.

TITLE OF CME ACTIVITY: _____

DATE: _____

TITLE OF PRESENTATION: _____

FACULTY MEMBER'S NAME: _____
(PLEASE PRINT OR TYPE)

- (1) I, the undersigned (or an immediate family member), have a financial arrangement or affiliation with a corporate organization offering financial support or grant monies for, or related to, this activity; and/or
 (2) I, the undersigned, have a financial relationship with a manufacturer of a product discussed in my presentation at this continuing medical education program — as follows:

(NOTE: There is no need to disclose the actual financial value of any affiliation.)

<i>Type of Affiliation / Financial Interest</i>	<i>Name of Corporate Organization</i>
Grants / Research Support	_____
Consultant	_____
Stock Shareholder (directly purchased)	_____
Honorarium	_____
Other Financial or Material Support	_____

- I have no relationships to disclose
- I agreed to the Terms and Conditions listed on the back of this form

- I intend to reference unlabeled/unapproved uses of drugs or products in my presentation (*specify product by name for which unlabeled use will be discussed*):

Signature _____

Date _____

TERMS AND CONDITIONS FOR FACULTY REGARDING COMMERCIAL SUPPORT RULES

Disclosure. Speakers/authors must complete and submit the Disclosure Statement located on the front side of this document prior to the presentation, and ensure that the Disclosure Statement is complete and truthful to the best of the presenter's knowledge. Faculty members are required to disclose any financial relationships they may have with a manufacturer of any product or class of products they discuss in an educational activity.

Fair Balance. Speakers/authors are required to prepare fair and balanced presentations that are objective and scientifically rigorous.

Unlabeled and Unapproved Uses. Presentations that provide information in whole or in part related to non-FDA approved uses for drug products and/or devices must clearly acknowledge the unlabeled indications or the investigational nature of their proposed uses to the audience. Speakers/authors who plan to discuss non-FDA approved uses for commercial products and/or devices must advise The Johns Hopkins University Office of CME of their intent.

Use of Generic versus Trade Names. Presenters should use scientific or generic names when referring to products in their lectures or enduring materials. Should it be necessary to use a trade name, then the trade names of all similar products or those within a class should be used.

Commercial Supporter Influence. Faculty members are not permitted to receive any direct remuneration or gifts from the commercial supporter(s) of this activity as it relates to this specific activity, nor should they be subject to direct input from a commercial supporter regarding the content of their presentations.