

## Policy and Procedure Manual



ENTITY	NUMBER
NYU Post Graduate Medical School	NYU PGMS-
MANUAL	EFFECTIVE DATE
Policy and Procedure	July 1, 2004
SUBJECT	REVISED
Commercial Support	NEW

## 1.0 PURPOSE

The Policy on Commercial Support<sup>1</sup> exists to provide guidance for staff, faculty and joint sponsors in order to implement and comply with ACCME's *Standards for Commercial Support of Continuing Medical Education* for activities sponsored by NYU Post Graduate Medical School (NYU PGMS).

## 2.0 POLICY

- 2.0 **Approval of Communication with Commercial supporters.** Course chairs and sponsoring departments must approve IN ADVANCE the terms and conditions of grants and exhibit arrangements through the CME Manager. Receipt of a reduced amount of a grant from a supporter is not subject to rejection by the course chair or department, as this action may bias other future grants affecting NYU in general.
- 2.1 **Adoption of the Standards for Commercial Support.** NYU PGMS fully supports and adopts the ACCME *Standards for Commercial Support of Continuing Medical Education* as its basis for relating to organizations that provide commercial support for CME activities or the overall CME Program.
- 2.2 **Letter of Agreement.** An NYU PGMS approved Letter of Agreement must be utilized whenever an activity receives commercial support. NYU PGMS must be directly involved in the contractual process between NYU PGMS and the organization providing commercial support.
- 2.3 **Fair-Balance.** All continuing medical education activities provided by NYU PGMS shall provide for an in-depth presentation that is independent, balanced, objective and scientifically rigorous.
- 2.4 **Input from Commercial Supporter.** NYU PGMS is solely responsible for the administration, content, quality and integrity of all continuing medical education activities. A planning committee for a CME activity may take into account

<sup>1</sup> A commercial supporter is defined as any entity providing funds or resources to a continuing medical education provider (ACME Policy 1996-B-07).

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recommendations from commercial supporters or other interested parties, but those recommendations are not to be a condition for receipt of commercial support grants. If a commercial supporter provides assistance with preparation of educational materials, these materials shall not advance the specific proprietary interests of the commercial supporter.

- 2.5 **Social Events.** In accordance with ACCME's Standards for Commercial Support (SCS Section 8a), NYU PGMS will use funds originating from the commercial supporter as stipulated in the Policy on Social Events at CME Activities. As such, commercial support funds may not be used to defray costs of any kind for guests of the primary registrant.
- 2.6 **Distribution of Materials.** The commercial supporter may be requested by NYU PGMS to assist in the promotion of the CME activity through the distribution of brochures or other similar materials. However the supporter may not assist in the distribution of enduring materials.
- 2.7 **Participation by Industry Representatives at Supported CME Activities.** Representatives from commercial supporters may attend an educational activity, but may not engage in sales activities in the room where the activity takes place. NYU PGMS reserves the right to limit the number of representatives attending an activity.
- 2.8 **Unlabeled/Unapproved Uses.** Faculty that 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 is required to disclose to the audience that the product is not labeled for the use under discussion or that the product is still investigational (see Policy on Disclosure).
- 2.9 **Acknowledgment of Commercial Support.** All corporate support will be acknowledged at the meeting. The CME office will establish a deadline for the receipt of signed Letters of Agreement for inclusion in the Commercial Support Acknowledgement page in the Syllabus. If the signed Letters of Agreement are not received before the deadline, the commercial supporter will be acknowledged in a handout on the day of the course.
- 2.10 **Gifts to Physicians.** NYU PGMS adopts the following policies with respect to gifts to physicians utilizing commercial support funds:
  - 2.10.1 Subsidies from the commercial supporter should be given directly to NYU PGMS in the form of an educational grant, rather than to individual physicians or faculty.

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2.10.2 Any gifts accepted by physicians individually should primarily entail a benefit to patients and should not be of substantial value. Text books, modest meals, and other gifts are appropriate if they genuinely serve an educational function. Cash and gift certificates are not acceptable forms of gifts.

2.10.3 No gifts should be accepted if there are strings attached.

2.10.4 Scholarships for physicians-in-training (such as medical students, residents, and fellows) are permissible as long as their selection is made by the academic or training institution.

### 2.11 Exhibits.

2.11.1 When commercial exhibits are part of the overall CME activity, arrangements for these exhibits should not influence planning or interfere with the presentation of CME activities. Exhibit placement should not be a condition for support for a CME activity.

2.11.2 No commercial promotional materials shall be displayed or distributed in the same room immediately before, during, or after a CME activity.

2.11.3 You cannot announce any offsite events, luncheons, dinners etc. that are being support by a commercial entity in the same room as the CME activity. Those events must only be publicized at the company's exhibit table.

2.11.4 Commercial exhibits are considered to be strictly promotional. Exhibitors are not considered commercial supporters unless they are specifically supporting the *actual* education and cannot be acknowledged on the course materials.

## 3.0 IMPLEMENTATION

3.1 NYU PGMS will routinely issue a faculty letter that advises instructors and moderators of requirements relative to the Standards for Commercial Support. The letter will include the following requirements: (a) presentations must be unbiased, scientifically rigorous and include a balanced view of therapeutic options; (b) faculty must disclose relevant financial relationships with any commercial supporter; (c) faculty must disclose relevant financial relationships with the manufacturers of products or competing products discussed in their presentation; and (d) faculty must disclose unlabeled or unapproved uses discussed in their presentation to the participants.

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- 3.2 NYU PGMS will issue to each instructor a Faculty Disclosure Form that will solicit information from the faculty relative to (a) disclosure of financial relationships with supporters and manufacturers and (b) their intended discussions of unlabeled or unapproved drugs or devices during their presentations. Information collected on the form shall include financial relationships in place over the preceding twelve month period. If instructors have nothing to report, that information must be reported to NYU PGMS.
- 3.3 CME activity promotional materials and educational handouts will, as a matter of routine, include acknowledgement of commercial support. With regard to handouts and enduring materials, such acknowledgement will be placed in the introductory sections of those materials so that participants may review this information prior to the commencement of the activity.
- 3.4 Disclosure of discussions of unlabeled or unapproved uses will be made in writing if at all possible and appear in introductory sections so that the learner will know this information prior to participating in the activity. In the case of journal-based CME, this notification may be placed at the end of the article for space considerations (pre-notification requirements can be met if a boxed notice is placed in the introductory pages of the journal directing the reader to the specific page(s) of the disclosure information).

### **APPROVALS:**

CME Committee: July 1, 2004