

August 10, 2007

## **Policies for Interactions Among Clinicians at Boston Medical Center and Boston University School of Medicine and Representatives of the Healthcare Industry**

### Introduction

*These policies are intended to apply to all BMC and BUSM employees and all trainees at BMC and BUSM who are directly engaged in the provision of clinical services (collectively referred to as "clinicians" below). **Although the focus of the guidelines is on the pharmaceutical and device industries, the policies apply to all commercial suppliers of clinical services or supplies.***

The leadership of the clinical departments of Boston Medical Center ("BMC") and Boston University School of Medicine ("BUSM") have developed the following policies for interactions among their clinicians and representatives of the pharmaceutical and device industries. The healthcare industries, particularly the pharmaceutical and device industries, play a vital role in drug discovery and in improving the public health. The clinicians at BMC and BUSM are eager to promote a mutually beneficial relationship with industry that facilitates discovery, evidence-based use of medications and devices, and that is characterized by the highest professional standards of rigor and integrity. These policies are intended to meet these goals by setting standards for the interactions between clinicians and representatives of the health care industries. We specifically seek to preserve and fortify the independence of our clinicians; ensure that we incorporate the most objective information in the care of our patients; slow the rising cost of healthcare; reduce the potential for real or perceived bias in our programs of clinical care and education; and ensure compliance with the law. The complexities of relationships with industry preclude us from identifying all circumstances in which a financial conflict of interest may arise or in which an interaction may be inappropriate. We believe that the guiding principles in unclear situations should be to protect the interests of our patients and the independence of the faculty. **The overriding goal of these policies is to ensure as much as possible that the integrity of our educational programs and clinical decision-making are not compromised by financial or other personal relationships with industry.** Clinicians must consciously and actively divorce clinical care decisions (including referrals and diagnostic or therapeutic management) from any perceived or actual benefits accrued or expected from any company (including, but not limited, to personal gifts, research funding, scholarships for CME attendance, or consulting agreements).

Adherence to the policies is important to avoid both conflict of interest in clinical practice and violation of the federal and state anti-kickback statutes and other laws. These policies will need to be revised in the future as the law and the expectations of the public and the medical profession evolve.

These policies augment BMC's and BUSM's policies on conflict of interest. In the case of clinicians, when these policies are more stringent than those policies on conflict of interest, these policies will apply. Since the BMC Conflict of Interest Policy and the BU Policy on Investigators' Conflicts of Interest, as administered by the BUMC Advisory Committee on Investigators' Conflicts of Interest, apply to all research activity, these policies are not intended to apply to conflicts of interest in research activity.

## **1. Provision of Compensation or Gifts from Industry to Clinicians**

- a. Clinicians may not accept any form of personal gift from industry or its representatives.
- b. Meals directly or indirectly funded by industry may not be provided at BMC or on the BUSM campus. In addition, clinicians should use discretion in participating in industry-sponsored meals off campus. Specifically, FPP physicians should not facilitate the attendance of trainees at meals off campus sponsored by industry or at educational events off campus sponsored by industry which are not accredited by the Accreditation Council for Continuing Medical Education (“ACCME”) or the American Dental Association Continuing Education Dental Recognition Program (“ADA CERP”).
- c. Clinicians may accept only fair market compensation for specific, legitimate services provided by him or her to industry. The terms of the arrangements, services provided, and compensation must be set forth in writing.
- d. Clinicians may not accept compensation for listening to a sales presentation (e.g., detailing) by an industry representative.
- e. Clinicians who are simply attending a Continuing Medical Education (“CME”) or other instructional activity, and are not speaking or otherwise actively participating or presenting at the meeting, may not accept compensation from companies either for attending or defraying costs related to attending the meeting.
- f. Clinicians who are involved in institutional decisions concerning the purchase of or approval of medications or equipment, or the negotiation of other contractual relationships with industry must not have any financial interest (e.g., equity ownership, compensated positions on advisory boards, a paid consultancy or other forms of compensated relationship) in the vendor that might benefit from the institutional decision. This provision is not intended to preclude a clinician's indirect ownership, through mutual funds or other investment vehicles, of equities in publicly traded companies .
- g. Clinicians may not receive any form of compensation for changing a patient’s prescription or using a specific device in a patient.
- h. As a general rule, industry representatives may not interact with trainees at BMC or on the BUSM campus. Interactions are allowed in limited circumstances, however, when the expertise of representatives is required for instruction in the use of a device and a faculty member is present to supervise the interaction.
- i. Clinicians may only accept support from industry for travel and related expenses to review a vendor’s products under circumstances that do not create an actual or perceived conflict of interest and are compliant with BU policy (<http://www.bu.edu/policies/gift/policy.html>).
- j. Industry representatives are not allowed in in-patient or out-patient care areas and must visit with clinicians by appointment only. Under limited circumstances, device industry representatives may be allowed in patient care areas at the request of a clinician to facilitate a clinical procedure involving a pertinent device. Under these circumstances, representatives must comply with all BMC patient care requirements and wear appropriate clothing and identification that distinguishes them from employed staff.

## **2. Provision of Scholarships and other Funds to BUMC Trainees**

Clinicians should ensure that support of educational programs for trainees by the pharmaceutical or device industries is free of any actual or perceived conflict of interest.

These funding mechanisms may include grants for educational initiatives, scholarships, reimbursement of travel expenses, or other non-research funding in support of scholarship or training. Specifically, the industry funding must comply with all of the following:

- a. The trainee is selected by the Department, Program, or Section.
- b. The funds are provided to the BMC or BUSM development offices, or, in the case of CME-accredited activities, to the CME office.
- c. The Department, Program, or Section has determined that the conference or training has educational merit.
- d. The recipient of the funds is not subject to any implicit or explicit *quid pro quo* (i.e., “no strings are attached”).

### **3. Provision of Free Drug Samples to Clinicians**

- a. Clinicians may accept free drug samples from industry for distribution to patients. Although distribution of free samples to patients is not prohibited, **all** distribution of free samples to patients must be administered by the BMC pharmacy.
- b. Free drug samples may never be sold.
- c. Free drug samples may not be used by clinicians for themselves, clinical staff, or family members.

### **4. Industry Support for Educational Events at BMC or BUSM**

Clinicians should be aware of the Standards for Commercial Support established by the ACCME and the ADA CERP. A complete description of the Standards of the ACCME to ensure independence in CME activities is available at [http://www.accme.org/dir\\_docs/doc\\_upload/68b2902a-fb73-44d1-8725-80a1504e520c\\_uploaddocument.pdf](http://www.accme.org/dir_docs/doc_upload/68b2902a-fb73-44d1-8725-80a1504e520c_uploaddocument.pdf).

**All continuing education events at BMC or BUSM must fully comply with ACCME guidelines (or where pertinent, to the ADA CERP) whether or not formal CME credit is awarded.** In order to comply, clinicians will need to become familiar with the ACCME guidelines, and a clinician organizing a continuing education activity should consult with the BUSM Office of Continuing Medical Education for guidance.

In addition to complying with the ACCME Standards (or where pertinent, ADA CERP), educational events supported by industry at BMC or BUSM must also comply with the policies described under Sections 1 and 2.

## **5. Guidelines for Delivering Industry-Supported Lectures or Participating in Legitimate Conferences and Meetings of Clinicians off the BMC or BUSM Campus**

Clinical meetings and scientific meetings sponsored by professional societies frequently derive a portion of their support from industry. Such support may give rise to inappropriate industry influence on the content of the conference or its attendees. Grants for meetings and conferences that originate from the company's marketing division may be particularly problematic. Industry support generally takes one of two forms and different standards apply in each case.

- a. First, industry may partially support meetings run by professional societies. Clinicians are expected to participate in meetings of professional societies as part of their CME and professional obligations. Nonetheless, faculty should be aware of the potential influence of industry on these meetings and attentive to the guidelines set forth below in evaluating whether and how to attend or participate in these meetings.
- b. A second type of meeting is fully supported by industry. These guidelines apply to all lectures, meetings, and related publications supported directly by industry, and CME activities fully supported by industry or managed by intermediate educational companies subsidized by industry. Clinicians may actively participate (*e.g.*, giving a lecture, organizing the meeting) in such meetings or lectures only if:
  1. Financial support by industry is fully disclosed at the meeting by the sponsor.
  2. The meeting or lecture's content, including slides and written materials, are determined by the clinician.
  3. The clinician delivering a lecture is expected to provide a balanced assessment of therapeutic options and should promote objective scientific and educational activities and discourse.
  4. The clinician is not required by the company sponsor to accept advice or services concerning teachers, authors, or other educational matters including content as a condition of the sponsor's contribution of funds or services.
  5. The clinician receives compensation only for the services provided and the compensation is fair market compensation.
  6. Time spent in preparing and delivering the lectures does not impair the clinician's ability to fulfill Departmental responsibilities.
  7. The clinician delivering the lecture explicitly describes all his or her related financial interests (past, existing, or planned) to the audience.
  8. The clinician makes clear to the audience that the content of the lecture reflects the views of the clinician and not those of BMC or BUSM.
  9. Clinicians should not facilitate the participation of trainees in industry-sponsored events that fail to comply with these standards.

## **6. Disclosure of Relationships with Industry**

- a. Clinicians must disclose all of their related financial interests, including past, existing or expected interests (*e.g.*, grants and sponsored research, compensation from consulting, speaker's bureaus, advisory boards; investments and ownership interests) to journal

editors in manuscripts submitted for publication, and audiences at lectures or presentations.

- b. Clinicians must disclose their actual and potential conflicts of interest related to any institutional deliberations and generally may not participate in deliberations in which he or she has an actual or potential conflict of interest. See Boston Medical Center Vendor Relations Policy (No. 9.16); Boston Medical Center Conflict of Interest Policy (No. 9.4); Boston University Conflict of Interest Policy (<http://www.bu.edu/ethics/conflict.pdf>).
- c. Clinicians with supervisory responsibilities for trainees or staff must ensure that the faculty's conflict or potential conflict of interest does not affect or appear to affect his or her supervision of the activities or responsibilities of the trainee or staff member.

## **7. Enforcement**

Department chairs are responsible for enforcement of these policies in their respective departments. For conflicts of interest involving a department chair, the Chief Medical Officer (CMO) is responsible for enforcement. The department chairs/CMO shall report serious violations of these policies to the BMC/BUSM Compliance Officers and President and CEO of BMC or the Dean of BUSM, as applicable.

The following references were utilized in the compilation of these Guidelines:

1. American Medical Association. Opinion of the Council on Ethical and Judicial Affairs, E-8.061 <<http://www.ama-assn.org/ama/pub/category/4001.html>> Accessed January 20, 2005.
2. Department of Health and Human Services, Office of Inspector General. OIG Compliance Program Guidance for Pharmaceutical Manufacturers. Fed Regist 2003;68:23731-43.
3. Pharmaceutical Research and Manufacturers of America. PhRMA Code on Interactions with Healthcare Professionals. Wash D.C., PhRMA, 2002.
4. Accreditation Council for Continuing Medical Education Report on Standards for Commercial Support accessed March 12, 2005 at [http://www.accme.org/dir\\_docs/doc\\_upload/68b2902a-fb73-44d1-8725-80a1504e520c\\_uploaddocument.pdf](http://www.accme.org/dir_docs/doc_upload/68b2902a-fb73-44d1-8725-80a1504e520c_uploaddocument.pdf)
5. Moses, H, et.al. *Collaborating with Industry-Choices for the Academic Medical Center*. N Engl J Med 347:1371-5, 2002.
6. Boston Medical Center Vendor (Pharmaceutical) Representatives BMC Policy and Procedure #18.30
7. Boston Medical Center Vendor Relations Policy (No. 9.16)
8. Boston Medical Center Conflict of Interest Policy (No. 9.4)
9. Brennan, TA, et al. Health Industry practices that create conflicts of interest. A policy proposal for academic medical centers. JAMA 295:429-433, 2006.

10. Coleman DL, et al. Guidelines for interactions between clinical faculty and the pharmaceutical industry: one medical school's approach. *Acad Med* 81:154-160, 2006.
11. Chimonas, S, Brennan, TA, Rothman, DJ. Physicians and Drug Representatives: Exploring the dynamics of the relationship. *Society of GIM* 22:184-190, 2007.
12. Guidelines for Interactions Among Yale Medical Group Physicians and the Pharmaceutical Industry