

**The University of Tennessee College of Medicine  
Graduate Medical Education Industry and Promotional Activities**

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**Effective 7/1/07**

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**Definition of terms**

Commercial interest: Shall include pharmaceutical, biomedical devices, equipment, and other health-related entities

Continuing Medical Education (CME): A conference or meeting held at an appropriate location, where the gathering is primarily dedicated, in both time and effort, to promoting objective scientific and educational activities and discourse and the main incentive for bringing attendees together is to further their knowledge on the topic(s) being presented. An appropriate disclosure of financial support and resolution of conflicts of interest should be made.

Detailing: Marketing that involves individual pharmaceutical or device sales representatives (detailers) meeting with doctors to promote specific medications or products

Faculty: All physicians and others with academic appointments, whether voluntary or salaried, engaged in teaching physicians in training

In-service education program: Informational presentation or discussion by industry representatives and others speaking on behalf of a company to provide scientific and educational information

Meals: Occasional meals (but no entertainment/recreational events) offered in a venue and manner conducive to informational communication providing scientific or educational value

Representatives (*i.e.*, “commercial interest representative”): Vendors, sales, and marketing professionals

**A. Principles**

The primary mission of the UT College of Medicine Graduate Medical Education clinical training programs is to prepare trainees to render patient-focused, competent, evidence-based, and responsible clinical care. One component of this training is the acquisition of basic and advanced knowledge of commercial products. A second component is to critically evaluate sources of medical information from both academic and commercial sources, and to determine their relative worth, recognizing that academic sources should be emphasized.

Physician conflicts of interest generated by commercial interest marketing activities should be resolved consistent with obligations to patient care and medical education.

Attending faculty and house staff are committed to intellectual rigor, objectivity and the practice of evidence-based medicine in the transmission of medical information.

Detailing should not inappropriately bias physician practice.

## **B. Guidelines**

### **1. Faculty**

- a) Faculty should model behavior consistent with ethical guidelines developed by responsible professional organizations (American Medical Association, Accreditation Council for Continuing Medical Education) regarding relationships between physicians and commercial entities.
- b) Regardless of venue or sponsorship, faculty must present only objective, balanced materials consistent with established norms of the ACCME and AMA.
- c) Faculty may not receive honoraria for activities involving medical education of trainees and house staff given on campus.
- d) Faculty may serve as consultants to commercial entities for clearly defined professional services.
- e) Faculty must disclose relevant financial or other relationships between faculty and commercial interests that might constitute conflict of interest when involved in commercially supported programs.

### **2. Residents**

- a) Residents may not organize or promote, either on campus or off campus, non-CME approved, commercially-driven educational activities without program director/chair approval.
- b) Residents may not attend detailing meals off campus or at ambulatory sites during work hours unless a faculty physician is present during the program.
- c) Residents may not engage in any detailing activities (including computer-based detailing), either on campus or off campus, for which they receive gifts or payments.
- d) Residents may not receive honoraria for participation in lectures or detailing programs including those described as peer groups, advisory boards, dinner lectures, etc.
- e) Residents may accept gifts directly related to professional activities. They may not receive cash or cash-equivalence gifts, or any gift with a monetary value greater than \$25 without approval of program director/chair (see item 7 below).
- f) Residents may attend social events associated with educational activities only if:
  - 1. The dollar amount spent on the attendee is modest.
  - 2. The educational portion of the conference accounts for a substantial majority of the total time accounted for by the educational activities and social events together.
  - 3. A faculty member is present.

### **3. Commercial Interest Representatives in the Hospital Setting**

Each of our participating hospitals has an individual policy related to vendor relationships/interactions. It will be the responsibility of faculty and residents to be familiar with individual hospital policies. Copies of these policies are available on the GME website.

#### **4. Commercial Support of CME Approved Educational Activities**

All educational activities approved for AMA Category 1 credit shall adhere to Accreditation Council for Continuing Medical Education (ACCME) Standards for Commercial Support. Such standards ensure independence; resolution of personal conflicts of interest; appropriate use of commercial support; appropriate management of associated commercial promotion, content and format without commercial bias; and disclosures relevant to potential commercial bias.

#### **5. Presentations by Commercial Interest Representatives in Outpatient Settings**

Presentations by commercial interest representatives may have specific value in terms of assisting faculty in educating trainees in analysis of promotional material and in recognizing marketing techniques. Presentations by representatives and attended by trainees in outpatient settings must conform to the following:

- a) All on-campus presentations by commercial interest representatives must be organized and directed by the department chair or designee.
- b) Attendees must include at least one faculty physician.
- c) Representatives must make promotional materials to be used during a meeting available to the faculty preceptor prior to the meeting in a time frame acceptable to the preceptor.
- d) A faculty member should be prepared to discuss the promoted material in an objective and evidence-based fashion or assign this responsibility to a trainee. This preparation may include critical review of the promotional material and presentation of additional or refuting studies referencing the promoted information with consensus panel statements, position papers, etc. (See attached guidelines.)
- e) The representative may remain for the discussion portion of the meeting at the discretion of the faculty physician in attendance.

#### **6. Educational Programs on Marketing and Promotion**

- a) The System-Based Lecture series of the UT GME program will include education about commercial/industry sales and promotions.
  1. An overview of the commercial interest industry: financials, participation in research and CME, lobbying size compared with other industries, marketing techniques and evaluation of promotional literature
  2. Techniques utilized to influence physician prescribing: review of research studies analyzing the results of vendor/sales/MD interactions
  3. Recognition of clinically relevant and irrelevant drug information, value of commercial industry presentations compared with other sources of information, and identification of omitted information.
  4. Ethical issues/conflicts of interest raised by interactions with industry.

## 7. Gifts

- a) Consistent with the AMA's Code of Medical Ethics "Gifts to Physicians from Industry," gifts from commercial interest companies must be limited to gifts with patient benefit, educational value, and be of insubstantial monetary value. Gifts of minimal value related to a faculty member's work are also permitted (*e.g.*, pens, notepads). Trainees may not accept gifts unrelated to professional activities.
- b) A grant or substantial gift (*i.e.*, greater than \$25) may be made only as an unrestricted grant through the College of Medicine, the department or individual program. All Letters of Agreement and/or contracts must be executed through the Office of Grants and Contracts (3 party agreements) of the Office of Research Administration. Chairs and program directors may not sign these agreements.
- c) Residents or faculty should not:
  - 1. Solicit or receive personal gifts from commercial interest companies.
  - 2. Allow representatives to conduct contests, drawings, raffles, or other activities that lead to personal gifts.
  - 3. Residents or faculty may receive competitive awards and scholarships funded by pharmaceutical companies if all control of recipient selection rests with an independent professional organization.
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## 8. Product Samples

Acceptance of sample medications and other products is an example of a promotional activity and therefore should be limited among the hospital's clinical departments and faculty practices. Sample products may be helpful to patients who have financial difficulty in obtaining needed medications. However, prescribing and distributing branded medications solely because of gratis availability is inappropriate.

- a) It may be acceptable to distribute a specific branded medication sample to treat a condition provided 1) the quality of care to the patient is no way compromised by selection of medication (*e.g.*, efficacy, risk profile, compliance, or cost) and 2) no acceptable generic alternatives exist.
- b) Physicians should not accept from pharmaceutical detailers conditions of face-to-face interaction in order to procure product samples.
- c) The physician (or designee) responsible for a clinical department or faculty practice determines the specific medication or product samples to be accepted for distribution.
- d) Consistent with AMA guidelines, faculty and residents may accept gratis medications for personal or family use for a trial to assess tolerance or efficacy, or for treatment of acute conditions requiring short courses of therapy. Neither faculty nor residents may accept gratis pharmaceutical medications or products for long term treatment of chronic conditions.

- e) Faculty or residents should not receive medication or other product samples (*e.g.*, infant formula), of monetary value greater than \$50/month/product for personal use.

## WITH RESIDENTS: AN OUTLINE FOR FACULTY PRECEPTORS

### A. Promotional material must be provided well in advance of the meeting with the pharmaceutical representative to ensure an informed and critical review:

1. Assign residents to perform a literature search for additional studies related to the claims made in the promotional materials.
2. For studies provided by pharmaceutical representatives, note the peer review standard/repute of the journal in which the studies are published.
3. Note the source of funding of the study.
4. Note whether results include intermediate outcomes and whether graphs contain “numeric distortion”.
5. Also note any extemporaneous claims made by the representative during his/her presentation regarding absolute and relative efficacy, safety, tolerability and ask for data to support these claims.

### B. During and after the presentation, identify commonly used sales techniques:

1. **Attention:** Get the attention of the prospect (physician) through some advertising or prospecting method. (LUNCH, pens, etc.)
2. **Interest:** Build the prospect’s interest by using various appeals and arguments.
  - APPEAL TO POPULARITY – both personal popularity or ‘friendship’, and external popularity-- “all the GI docs at St. Elsewhere use it”.
  - APPEAL TO AUTHORITY – “The Chief of Cardio at St. Elsewhere has had great success with this drug”.
  - APPEAL TO EMOTION – Gratitude, obligation, friendship, etc.
  - THE NON SEQUITUR – fallacy of irrelevant conclusions, or fallacy of ignoring the issue – “ACE inhibitors improve survival in CHF... our ACE inhibitor [*not FDA approved for CHF*] is more effective in controlling blood pressure than X’s drug”.
3. **Desire:** Build the prospect’s desire for the product by describing its features and letting them sample it (free samples).
4. **Conviction:** Increase the prospect’s desire for the product by statistically proving the worth of the product. (See comments above regarding literature/studies). Use testimonials from happy customers.
5. **Action:** Encourage the prospect to act. This is the *closing*- asking for the prospect’s commitment to try or prescribe it