Guidelines on Industry Activities for the David Geffen School of Medicine at UCLA and UCLA Health

Introduction

The purpose of these guidelines is to establish clear direction for faculty, staff, and trainees of the David Geffen School of Medicine at UCLA, and UCLA Health, in their interactions with industry representatives. Relationships with commercial interests in the health care sector frequently promote the educational, clinical, and research missions of the School of Medicine and UCLA Health. These interactions also may, however, create conflicts of interest, improper influence on decision-making, or the appearance of impropriety. Recent research indicates that industry activities, such as the provision of gifts of nominal value, may affect health care provider behavior and decisions. The Faculty Executive Committee of the School of Medicine believes that these guidelines will enhance positive and constructive working relationships with industry and minimize any questions about improper influence of sales and marketing activities in the School.

I. Gifts and Compensation Provided by Industry

- A. Gifts are defined as items of any value received by a member of the faculty, staff, or student body for which the recipient has not provided adequate consideration in return. Examples of gifts under these guidelines would include pens, notepads, textbooks, meals, and payment for attending a meeting. This definition is somewhat broader than that contained in the State Fair Political Practices Act (FPPA), which governs University of California employees and aims to remove bias from their decisions. These guidelines supplement the provisions of the FPPA and University Business and Finance Bulletin G-39 (Conflict of Interest Policy) in order to reduce the potential influence of vendors on the decisions made by faculty, staff, and trainees in the School of Medicine. Honoraria and associated travel for a specific service rendered (e.g., speaker's fee) are not considered gifts because these are payments for a service. Competitive grants also are not considered gifts. Informational materials that have been produced under Accreditation Council for Continuing Medical Education (ACCME) guidelines or published under a peer review process are not considered gifts. UCLA faculty, staff, and students should be familiar with the University's Conflict of Interest Policy (http://www.ucop.edu/ogc/coi/text.html) and University general gift guidelines (http://www.ucop.edu/ogc/coi/appendd.html).
- B. Gifts from industry should not be accepted anywhere on the UCLA campus or at any clinical facility operated by the UCLA Health. In addition, UCLA faculty, staff, and trainees should not accept gifts at any non-UCLA-operated clinical facilities such as other hospitals or clinics. The School of Medicine strongly encourages faculty and non-faculty medical staff at any affiliated program never to accept any personal gift from industry at any location under any circumstances.

- C. Individuals must continually strive to avoid the appearance that clinical care decisions are influenced by outside commercial interests, or by any benefits expected or received from any company. All offices and clinical care areas (i.e., rooms in an outpatient clinic, patient waiting areas, or hospital space) should be free of any materials that bear the name of a particular product or company (e.g., pens, papers, notepads, etc.). Individuals may not accept gifts, gratuities, meals, or compensation for listening to a sales talk by an industry representative, for prescribing or changing a patient's prescription, or for attending a CME or non-CME activity (unless the individual is a speaker or is otherwise actively participating or presenting at the event).
- D. Pharmaceutical or device samples have the potential to inappropriately influence clinical care of patients. For example, samples may encourage a physician to prescribe a new branded costly medication when older generic inexpensive medications may have the same or greater proven efficacy and safety. At the same time, the ready availability of no-cost samples may be of benefit for patients of limited financial means or where treatment adherence is an issue. UCLA faculty, staff, and trainees should utilize pharmaceutical or device samples (i.e., glucose meters) only within policies established by UCLA Health (i.e., logging in of samples), and when these samples clearly enhance patient care. Samples should not be used simply as a convenience or because of the encouragement of industry representatives. Samples should not be solicited or obtained by faculty, staff or trainees for personal use or for use by family members.

II. Access to Clinical and Non-clinical Areas by Sales and Marketing Representatives

- A. UCLA is firmly committed to protecting the privacy of our patients. Individuals who are not involved in the care of the patient will not be allowed to be present without the patient's consent while the patient is being examined or otherwise treated. The presence of device vendor representatives in a clinical area such as an Operating Room or Procedure Room to assist with device implantation, testing or settings will be listed as part of the treatment team in the Operating Room log maintained in the patient's medical record, and must be identified on the Surgical Informed Consent form.
- B. Sales and marketing representatives are not permitted in any clinical areas except to provide in-service training on devices and other equipment already purchased, or to provide demonstrations that may be of benefit to patients and where no purchase is required. Under those circumstances, representatives are allowed only by appointment.
- C. Sales and marketing representatives are permitted in non-clinical areas by appointment only. Appointments will normally be made for such purposes as:

- 1. In-service training of personnel for research or clinical equipment or devices already purchased;
- 2. Evaluation of new purchases of equipment, devices, or consideration of addition of new pharmaceuticals to the hospital medication formulary.
- 3. While appointments may be made at the discretion of any faculty member, the overall activity of sales and marketing representatives is subject to the oversight of division chiefs, department chairs, medical staff leadership, and other designated officials of the SOM and UCLA Health.

III. Industry Support for Educational and Other Professional Activities

- A. All events that receive industry support and are sponsored by the School of Medicine or UCLA Health must be compliant with ACCME Standards for Commercial Support *whether or not CME credit is awarded*. This includes not only educational events, but also other professional activities such as faculty or staff meetings, regardless of whether these events occur on or off the UCLA campus.
- B. Industry grants to support educational or professional activities must comply with ACCME Standards and must be administered by departments or divisions and not by individual faculty. Faculty, staff, and trainees should become familiar with the ACCME Standards for Commercial Support. The Standards may be found at www.accme.org. Divisions and departments are advised to maintain records of compliance with the ACCME Standards. Guidance on interpretation of ACCME standards may be obtained from the Office of Continuing Medical Education in the School of Medicine or, for the clinical neurosciences, the Office of Professional and Community Education in the Semel Institute.
- C. Industry representatives may not directly provide meals or other types of food for any educational or professional activity of the School of Medicine, anywhere on the UCLA campus or at any facility operated by UCLA Health. Faculty, staff, and trainees are strongly encouraged not to accept such meals at any location under any circumstances.
- D. Faculty and medical staff should evaluate very carefully their own participation in meetings and conferences that are fully or partially sponsored or run by industry because of the high potential for perceived or real conflict of interest. Individuals should actively participate in meetings and conferences supported in part or in whole by industry (e.g., giving a lecture, organizing the meeting) only if the meetings and conferences follow these guidelines:

- 1. Financial support provided by industry is fully disclosed by the meeting sponsor;
- 2. The lecturer is solely responsible for the content of the lecture. The lecturer is expected to provide a fair, balanced, and where possible evidence-based assessment of therapeutic options and to promote balanced discussion of the topic. The lecturer prepares his or her slides and other educational materials and does not delegate this to industry sponsors;
- 3. The meeting organizer is not required by an industry sponsor to accept advice or services concerning speakers, content, or meeting organization as a condition of the sponsor's contribution of funds or services;
- E. These provisions do not apply to meetings of professional societies that may receive partial industry support, or other meetings governed by ACCME Standards, where outside organizations take responsibility for ensuring that presentations are free of commercial influence.
- F. Industry sales representatives have the same access to the official educational offerings of the University as other members of the general public. Generally, these are official courses of the University or CME programs in accordance with ACCME guidelines. Faculty or departments should not offer preceptorships to industry representatives without involvement of the Office of Continuing Medical Education in the School of Medicine or, for the clinical neurosciences, the Office of Professional and Community Education in the Semel Institute.

IV. Student and Other Trainee Interactions with Industry

- A. All students, residents, trainees, and staff should receive training from the School of Medicine regarding potential conflicts of interest in interactions with industry.
- B. Industry support of students and trainees should be free of any actual or perceived direct benefit to the company providing the funds. Funds must be provided to an academic unit of the School of Medicine specifically for the purpose of education and must comply with all of the following provisions:
 - 1. The School of Medicine department, program or division must oversee the activity to be funded, and certify that the funded activity enhances the goals of the training program.
 - 2. The School of Medicine department, program or division must have sole discretion to determine how the funds are to be used. If the funds are intended to support educational activities or professional expenses of a trainee or trainees, the department, program, or division should have total discretion in deciding which students or trainees receive support.

C. These provisions do not apply to educational programs for trainees at national or professional society meetings, awards, or travel grants presented by professional

societies, where outside organizations take responsibility for ensuring that the activities are free of commercial influence.

V. Faculty, Staff, and Trainee Disclosure of Relationships with Industry

- A. In scholarly publications, faculty, staff, and trainees must disclose their related financial interests in accordance with the International Committee of Medical Journal Editors (www.icmje.org).
- B. Faculty with supervisory responsibilities for students, residents, trainees or staff should ensure that conflicts or potential conflicts of interest do not affect or appear to affect his or her supervision of the students, resident, trainee, or staff member.
- C. Faculty or staff having any personal financial interest or indirect financial interest as defined by University policy, or whose spouses, registered domestic partners, or dependent children having such interests, in companies that might substantially benefit from the decisions made within their University duties must refrain from participating in or influencing these decisions under the provisions of the California Political Reform Act. This does not apply to financial interests in investment funds where the individual does not have separate and direct control over the investment in the company. Provisions of the act may be viewed at http://www.ucop.edu/ogc/coi/disqual.html.
- D. All faculty should fulfill their obligation to disclose outside professional activities to the School of Medicine under the provisions of the Academic Personnel Manual section 025. The provisions of this policy may be viewed at http://www.apo.ucla.edu/call/append19.htm.
- E. For disclosure requirements related to educational activities, faculty, staff, and trainees should abide by the ACCME Standards for Commercial Support (www.accme.org).

VI. Ghostwriting

Faculty, staff, and trainees in the David Geffen School of Medicine are responsible for all professional content listing them as authors, including publications or presentations of any kind, oral or written, regardless of medium. Such content may never be ghost-written by industry representatives. Ghostwriting, as defined by the AAMC, is the provision of written material that is officially credited to someone other than the writer of the material.