

Policy on Conflicts of Interest and Interactions between the Health Care Industry and Personnel of the Vanderbilt University Medical Center and its Affiliated Entities*

Interactions between the health care industry and the university community have led to numerous societal benefits. Among these are collaborative endeavors which promote research, education, and patient service initiatives which might not occur by other means. Such interactions when unregulated and uncontrolled, however, have the potential for creating conflicts that have adverse effects on the missions of the university. The purpose of this policy is to establish guidelines for interactions with pharmaceutical companies, medical device companies, medical supply vendors, and their agents (hereafter referred to as the Health Care Industry) for faculty, staff, students, and trainees at the healthcare facilities associated with Vanderbilt University (hereafter referred to as VUMC personnel). The overarching objective of this policy is to minimize the likelihood for conflict situations that might inappropriately influence patient care and/or medical education. These guidelines are based on the understanding that physicians and other healthcare providers have special obligations to patients and trainees and that these obligations should not be compromised by the presence or appearance of conflicts with commercial interests or by Health Care Industry marketing practices.

This policy statement supplements existing Medical Center and University policies governing conflicts of interest and relationships with industry, with particular attention to the VUMC Vendor Policy. In all situations where this policy is more restrictive than existing policy, this policy shall control. It is expected that VUMC personnel will be familiar with this policy and of the expectations for industry/vendor compliance.

I. Gifts and Compensation

- A. VUMC personnel shall not accept or use personal gifts from Health Care Industry representatives, regardless of the nature or the value of the gift. In addition, to avoid the appearance of impropriety, VUMC personnel will not offer or provide gifts to Health Care industry representatives. This includes, but is not limited to, companies currently engaged in or proposing to do business with Vanderbilt. A list of Health Care Industry vendors currently doing business with Vanderbilt may be reviewed at [insert web link here].
- B. VUMC personnel may not accept gifts or compensation for listening to a sales talk by a Health Care Industry representative, using/prescribing a particular product or service, or for prescribing medications or changing a patient's prescription.
- C. VUMC personnel may not accept meals or other hospitality funded directly by the Health Care Industry, whether on campus or off campus. Meals offered at national meetings (or at associated satellite symposia approved by meeting organizers) may be accepted so long as the activity linked to the meal is educational, scientific, or consultative, and not marketing. With the exception of grants specifically provided in support of CME activities (see Section II.A.), department chairs, division chiefs, center directors, institute directors, and CEOs (or their designees) may elect to apply funds from Health Care Industry sources as unrestricted gifts towards meals and refreshments at on-campus regularly scheduled meetings which are in the furtherance of the operational unit's missions (see Section II.C.). These gifts are normally tax exempt, and as such may only be accepted through the VUMC Development Office. While there may be acknowledgement by unit leadership of the source of sponsoring funds at such events, marketing/sales representatives of the Health Care Industry may not attend. Similarly, exhibition or distribution of Health Care Industry products, services, devices, promotional materials, and/or educational materials selected or provided by the sponsor may not occur within, or adjacent to, such events.
- D. In certain instances, travel expenses or meals may be offered by the Health Care Industry related to necessary education regarding equipment, products, or other medical devices purchased previously by VUMC. Generally, these activities are foreseeable and should be addressed by specific language in the purchasing contract. VUMC personnel may accept such offers if there exists a stipulation in the concluded purchasing contract specifying the party to be responsible for such post-purchase training expenses. Under no circumstance, may VUMC personnel accept offers from the Health Care Industry to

pay for travel, meals, or other expenses which are related to procurement activities by VUMC and/or VUMC personnel.

- E. VUMC personnel may not accept compensation from the Health Care Industry, including the defraying of costs, for simply attending a CME or other activity (i.e. if the individual is not speaking or otherwise actively participating at the event).
- F. Consulting arrangements that pay VUMC personnel a guaranteed amount without any associated duties (e.g. scientific advisory boards that do not meet regularly and provide scientific advice) shall be considered gifts and are consequently prohibited.
- G. These guidelines are not meant to discourage constructive scholarly interchange between Vanderbilt personnel and Health Care Industry research and development efforts. However, while pursuing such activities, VUMC personnel must follow University guidelines relating to consulting and may accept only fair market compensation for specific, legitimate services provided to industry with payment commensurate with time and effort.
 - 1. The terms of the arrangements, services provided, and compensation must be set forth in writing.
 - 2. If one consulting relationship will pay the individual in excess of \$10,000 in consulting fees over any continuous 12 month period, prior review and written approval must be received from the department chair (for faculty and academic departmental staff), appropriate Associate Dean (for students, residents, fellows, or post-doctoral fellows), or the appropriate CEO/ CEO's designee (for medical center staff).
 - 3. All consulting relationships with entities which have any other type of relationship with Vanderbilt (e.g., vendor, research sponsor, source of gifts, etc.) must be reported by faculty and staff using the appropriate annual COI disclosure tool.
 - 4. In some instances, it may be mutually desirable for VUMC personnel to provide consulting services to a company in the Health Care Industry as a component of their Vanderbilt duties. An example of this might be a collaborative project using Vanderbilt space, resources, and/or personnel for research or for development of innovative technologies, devices, or treatments. Such services may be provided only under a contract which specifies the terms for such services and that payment will be made to Vanderbilt rather than to the individuals. Advice should be sought early in developing any such proposal from the Office of Research, Office of Grants and Contracts Management, the IRB, the Office of University Counsel, and the relevant Conflict of Interest Office, as appropriate.
 - 5. When Vanderbilt personnel are involved in providing education to Health Care Industry personnel (or to other persons identified or sponsored by the Health Care

Industry) and such activity will utilize any Vanderbilt facilities, space, resources, equipment, and/or subordinate Vanderbilt personnel, such activities will occur only under a services agreement contract between the sponsor and Vanderbilt which defines the scope of the intended activities and the compensation for same.

- H. VUMC personnel may not participate in or receive compensation for talks supported directly by the Health Care Industry or its agents (e.g., Medical Education Companies) if either: a) the selection of speaker, topic, and/or audience is determined by an entity which provides speakers only for events supported or sponsored by the Health Care Industry, or b) if the content of the lectures given is subject to any form of prior review or approval by either representatives of the Health Care Industry or event planners contracted by the Health Care industry, or c) the content of the presentation is not based on a balanced review of the best available scientific evidence. In essence, the lecturer is expected to determine the lecture's content, including slides and written material, and to provide a balanced assessment of therapeutic options. Specifically prohibited are talks in which the discussant refers predominantly to or promotes a specific drug, device, or service which is manufactured and/or marketed by the sponsor of the talk or its affiliate. This item does not restrict the opportunity for VUMC personnel to discuss their own scholarship as consultants to a company and to accept compensation and meals at such times. Particular caution should be exercised by VUMC personnel when functioning as speakers in the following situations:
1. If the presentation is for a general audience and the content relates to a subject for which the speaker receives research support from the sponsoring company.
 2. VUMC personnel are reminded of the restrictions on promotion of drugs or devices for indications which have not been approved by the FDA. An appearance of impropriety may develop when an individual gives lectures financed by the Health Care Industry on such unapproved indications. Thus, VUMC personnel may not be compensated by the Health Care Industry for disseminating information regarding off-label uses in lectures that promote such unapproved uses. The appearance of a conflict of interest may also occur when VUMC personnel are financed to perform research on unapproved indications (perfectly legitimately) and also are receiving payments for lecture and/or consulting from the same company. Consequently, such arrangements are prohibited.
- I. Upon implementation of this policy, VUMC personnel who have existing relationships with the Health Care Industry which are not compliant with this policy will take action to sever any such relationships or modify them to become compliant within one year.

II. Support for Educational and Other Professional Activities

- A. All educational events sponsored by VUMC and its affiliates must be compliant with ACCME Standards for Commercial Support whether or not CME credit is awarded. Use of CME certifying entities other than the Vanderbilt Division of Continuing Medical Education is prohibited if doing so would result in being out of compliance with these guidelines.
1. Educational grants that are compliant with the ACCME Standards may be received from the Health Care Industry, but must be administered by departments, centers, institutes, or divisions and not by individuals.
 2. The Division of Continuing Medical Education should be informed at the time of submission of requests for grants to support educational events. Agreements governing grants supporting educational events must receive prior approval by the Division of Continuing Medical Education.
 3. Divisions and departments must maintain records of compliance with ACCME Standards in a manner consistent with the guidelines of the Division of Continuing Medical Education.
- B. Provision of funds from Health Care Industry sources to support activities by VUMC personnel (i.e., scholarships, reimbursement of travel expenses, or other non-research funding in support of scholarship or training) must be free of any actual or perceived conflict of interest, whether the funds are provided directly to Vanderbilt or indirectly through industry grants to professional organizations.
1. Industry may not earmark contributions to fund specific recipients or to support specific expenses.
 2. The funds must be provided to the department or the sponsoring professional organization rather than directly to the trainee.
 3. The VUMC personnel must be selected according to clear criteria.
 4. The department must determine that the conference or training has educational merit.
 5. The recipient of the funds must not be subject to any implicit or explicit *quid pro quo*.
- C. Department chairs, division chiefs, center directors, institute directors and senior leadership figures overseeing faculty and staff activities must report all unrestricted gifts, except those supporting certified CME activities as referenced above, to the VUMC Development Office with indication of the amount and the accounts into which the funds have been deposited.

1. Any such funds are to be received as gifts. Any stipulation as to use must be generic, e.g. house staff education, house staff library, and there is to be no explicit or implied *quid pro quo* regarding the purpose to which such gift funds will be applied.
2. There will be an annual reporting of any such funds accepted together with an itemized record detailing how such funds were spent.

III. Display of Industry Provided Promotional Items

- A. Promotional items which incorporate or display a product or company logo of a Health Care Industry entity must not be used or displayed on the VUMC campus. This prohibition shall include exhibitions by industry representatives at, or adjacent to, certified CME activities. This prohibition does not include:
 1. Materials and equipment purchased by Vanderbilt where awareness of the displayed company or branding logo is helpful in identification and/or safe use of the product.
 2. Materials presented at VUMC approved vendor fairs which allow VUMC personnel to compare and contrast products/services from more than one vendor.
 3. Products in public areas which have been approved by VUMC for on-site sale to the public.
- B. It is desirable that materials used or provided by VUMC personnel for patient education be devoid of Health Care Industry logos, branding, and marketing content. When it is not practical to remove or conceal logos or branding information, or when doing so would fundamentally compromise the quality of patient/family education, such materials may be utilized subject to the following requirements:
 1. The materials to be used have been reviewed and approved by leadership in the practice area for use in education.
 2. Educational materials linked to coupons or discounts for drugs, medical devices, or other goods or services to be purchased by the patient are prohibited.
 3. Educational materials linked to referral to a non-Vanderbilt vendor or supplier of health care goods or services are prohibited.
 4. Branded educational materials/manuals which are intended to promote safe and appropriate use of a medication or medical device are permissible so long as there has already been a clinical judgment that the product or device is best for the care of an individual patient.
- C. While on the VUMC campus and while off-campus during activities when representing VUMC, VUMC personnel will not wear or otherwise display upon their persons any visible article of clothing, uniform, badge, pin, sign, or other item which displays the name of a non-Vanderbilt health care service, health care product, or company logo.

This restriction may be waived for special charitable or philanthropic events with the expressed consent of the Associate Vice Chancellor for Medical Center Communications. Specifically excluded from this restriction are:

1. Photo identification badges from other health care facilities.
2. Logos from non-profit and/or professional organizations which promote health in general or promote research, prevention, treatment and/or education in a specific disease or health area.

IV. Consequences of Non-Compliance

- A. In most instances, the first episode of non-adherence to this policy will be met with an educational response directed at the individual circumstance.
- B. Repetitive and/or flagrant disregard for this policy may be considered misconduct and will subject VUMC personnel to the possibility of disciplinary action.

Policy Effective Date: July 1, 2009