

***Policy on Conflicts of Interest and Interactions
between Representatives of Certain Industries and
Faculty, Staff and Students of the Schools of the Health Sciences and
Personnel Employed by UPMC at all Domestic Locations***

Date Issued: November 12, 2007

Effective Date: February 15, 2008

The University of Pittsburgh Schools of the Health Sciences (collectively “SOHS”) and the domestic locations of the University of Pittsburgh Medical Center (“UPMC”) share a goal to improve the health of the public through the creation and dissemination of knowledge about the mechanisms and treatment of human disease, and to employ this knowledge in the delivery of effective and efficient clinical care. This shared mission requires that faculty, students, trainees, and staff of the SOHS and physicians and other UPMC employees at all domestic locations interact with representatives of the pharmaceutical, biotechnology, medical device, and hospital equipment supply industry (hereinafter “Industry”)¹, in a manner that advances the use of the best available evidence so that medical advancements and new technologies become broadly and appropriately used. While the interaction with Industry can be beneficial, Industry influence can also result in unacceptable conflicts of interest that may lead to increased costs of healthcare, compromise of patient safety, negative socialization of students and trainees, bias of research results, and diminished confidence and respect among patients, the general public and regulatory officials. Because provision of financial support or gifts, even in modest amounts, can exert a subtle but measurable impact on recipients’ behavior, the SOHS and UPMC have adopted the following policy to govern the interactions between Industry and SOHS and UPMC personnel.

There is a growing body of evidence demonstrating the adverse consequences of interactions between healthcare providers and Industry,² including practices such as receipt of small gifts, that have traditionally been considered acceptable by professional standards, such as the ethical opinions of the American Medical Association’s Council on Medical and Judicial Affairs. While healthcare professionals may not believe that they are personally biased by Industry³, detailing by Industry representatives is designed to sell products and advance the interests of Industry’s shareholders. This policy has been designed on the basis of the best available literature on conflict of interest and is intended to provide a set of guiding principles that members of the SOHS and UPMC communities as well as representatives of Industry can use to assure that their interactions result in optimal benefit to clinical care, education and research, and maintenance of the public trust. This policy is designed to affect the behavior and practices of Industry, as much as the behavior of University and UPMC personnel. While valuable and meaningful

¹ While potential for conflict also exists with respect to interactions with other vendors (for example, providers of research equipment or laboratory supplies), existing policies, such as University Policy No. 05-02-02, Conflict of Interest and Procurement Relationships, the University Code of Ethics, Policy No. 05-02-03, and UPMC Policy on Conflict of Interest No. HS-LE-0002, apply to such interactions.

² See, e.g., Brennan TA, Rothman DS, Blank L, Blumenthal D, et al., Health Industry practices that create conflicts of interest: a policy proposal for academic medical centers. *JAMA* 2006; 295:429-33. Dana J, Lowenstein G, A social science perspective on gifts to physicians from Industry. *JAMA* 2003; 290:252-2; Chren MM, Landefeld CS, Physicians’ behavior and their interactions with drug companies: a controlled study of physicians who requested additions to a hospital drug formulary. *JAMA* 1994; 271:684-9.

³ This may explain the apparent pervasiveness of such relationships, particularly in some fields. See Campbell EG, Green R, et al. A National Survey of Physician-Industry Relationships, *N Engl J Med* 2007; 356:1740-1750.

interactions between Industry and academic medical centers can occur, the provision of gifts, food, or other blandishments add nothing to the substance of the exchange, and leave both parties subject to questions of integrity and commitment to professional practice responsibilities.

A. *Scope of Policy*

This policy applies to all faculty, staff, and students of the SOHS, and to all healthcare professionals and staff employed and/or contracted by domestic locations of UPMC, and to all facilities owned or controlled by the SOHS and all clinical facilities owned or controlled by UPMC. While this policy addresses many aspects of Industry interaction, it supplements the existing conflict of interest policies of the University of Pittsburgh, particularly as they apply to research conflicts of interest:

- Policy on Outside Employment:
<http://www.pitt.edu/HOME/PP/policies/02/02-06-01.html>
- Conflict of Interest Policy for Faculty, Scholars, Researchers, Research Coordinators/Staff
<http://www.pitt.edu/HOME/PP/policies/11/11-01-03.html>
- Policy on Conflict of Interest and Procurement Relationships:
<http://www.pitt.edu/HOME/PP/policies/05/05-02-02.html>

This policy also supplements existing UPMC policies, including but not limited to:

- UPMC Conflict of Interest Policy No. HS-LE-0002
- UPMC Guidelines for Purchasing Policy No. HS-MM-0300
- UPMC Presbyterian Shadyside Policy on Dispensing of Medication Samples, No. CP-19

In all cases where this policy is more restrictive than a University or UPMC conflict of interest policy, this policy shall control.

This policy applies to interactions with all sales, marketing, or other product-oriented personnel of Industry, including those individuals whose purpose is to provide information to clinicians about company products, even though such personnel are not classified in their company as “sales or marketing.”

B. *Statement of Policy*

It is the policy of the SOHS and UPMC that clinical decision-making, education, and research activities be free from influence created by improper financial relationships with, or gifts provided by, Industry. For purposes of this policy, “Industry” is defined as all pharmaceutical manufacturers, and biotechnology, medical device⁴, and hospital equipment supply industry entities and their representatives. In addition, clinicians and their staffs should not be the target of commercial blandishments or inducements – great or small – the costs of which are ultimately borne by our patients and the public at large. These general principles should guide all potential relationships or interactions between SOHS and UPMC personnel and Industry representatives. The following specific limitations and guidelines are directed to certain specific types of interactions. For other circumstances, SOHS and UPMC personnel should consult in

⁴ For purposes of this Policy, the definition of “medical devices” will follow the definition and any available guidance related thereto of the Federal Safe Medical Device Act of 1990, as amended, (21 CFR 821.1, <http://www.fda.gov.cdrh/comp/guidance/169.html>).

advance with their deans or department chairs (in the case of the SOHS faculty and personnel) or their administrators (in the case of UPMC personnel) to obtain further guidance and clarification. Charitable gifts provided by industry in connection with fundraising done by or on behalf of UPMC or SOHS shall be subject to other policies adopted from time to time by UPMC, SOHS or foundations fundraising on their behalf.

C. *Specific Activities*

1. Gifts and Provision of Meals

SOHS and UPMC personnel shall not accept or use personal gifts (including food) from representatives of Industry, *regardless of the nature or dollar value of the gift.*

Although personal gifts of nominal value may not violate professional standards or anti-kickback laws, such gifts do not improve the quality of patient care, may subtly influence clinical decisions, and add unnecessary costs to the healthcare system. Gifts from Industry that incorporate a product or company logo on the gift (e.g., pens, notepads or office items such as clocks) introduce a commercial, marketing presence that is not appropriate to a non-profit educational and healthcare system.⁵ Meals or other hospitality funded directly by Industry may not be offered in any facility owned and operated by the SOHS or UPMC.

SOHS and UPMC personnel may not accept meals or other hospitality funded by Industry, whether on-campus or off-campus, or accept complimentary tickets to sporting or other events or other hospitality from Industry. Modest meals provided incidental to attendance at an off-campus event that complies with the provisions of subsection 6, below, may be accepted.

Industry wishing to make charitable contributions to the SOHS or UPMC may contact the Medical and Health Sciences Foundation or other charitable foundations legally organized to support UPMC hospitals or other UPMC entities. Such contributions shall be subject to any applicable policies maintained by UPMC, SOHS, and the receiving organizations.

2. Consulting Relationships

The SOHS and UPMC recognize the obligation to make the special knowledge and intellectual competence of its faculty members available to government, business, labor, and civic organizations, as well as the potential value to the faculty member, the University, and UPMC.

However, consulting arrangements that simply pay SOHS or UPMC personnel a guaranteed amount without any associated duties (such as participation on scientific advisory boards that do not regularly meet and provide scientific advice) shall be considered gifts and are consequently prohibited.

In order to avoid gifts disguised as consulting contracts, where SOHS or UPMC personnel have been engaged by Industry to provide consulting services, the consulting contract must provide specific tasks and deliverables, with payment commensurate with the tasks assigned. All such

⁵ This provision does not prohibit acceptance of items bearing Industry logos provided as part of an off-site educational program (such as a meeting of a professional society), including name tag lanyards, totes, etc., where the items are provided incidental to attendance, the items are of nominal value, and the items are not used on UPMC or University premises.

arrangements between individuals or units and outside commercial interests must be reviewed and approved prior to initiation in accordance with appropriate University or UPMC policies.

For SOHS personnel, consulting relationships with Industry may be entered into only with the prior permission of a faculty member's dean, department chair (in the case of the SOHS faculty), or administrator. In addition, prior review and written approval from the faculty member's dean is required if consulting relationships with any one company (including the parent and subsidiary companies) will pay the faculty member in excess of \$10,000 in any twelve-month period. For employees of UPMC who are not faculty, prior written approval of the appropriate supervisor within UPMC is required for any outside consulting. The SOHS and UPMC reserve the right to require faculty and employees to request changes in the terms of their consulting agreements to bring those consulting agreements into compliance with SOHS and/or UPMC policies.

3. Drug or Device Samples

The provision by manufacturers of "free" samples of prescription drug or device products is a marketing practice designed to promote the use of these products and to gain access to prescribers to influence their behavior⁶. Studies from the literature quite convincingly demonstrate the effectiveness of this technique to boost sales. At the same time, this practice provides invaluable assistance to some patients to quickly begin a course of treatment or to determine which therapeutic option is most beneficial for that patient. Free samples also have been responsibly incorporated into the evidence-based decision making of some individual and group practices. While societal benefits result from the availability of medications at the point of care, sampling is also accompanied by regulatory and security concerns, poses potential safety risks for patients, and encourages prescribing of new, high cost medications whose safety and efficacy may not be different from existing treatments. In addition, the manufacturers' cost of producing the specially packaged samples and distributing them to physicians via personal couriers (company representatives), introduces a substantial expense into the overall consumer drug cost, estimated to have been over \$15 billion in 2005. (Pharmaceutical Executive, October 2005).⁷ In addition, the costs to the physician's practice associated with managing the inventory and storing the samples may increase provider and overall healthcare costs.

Application of the dual guiding principles given above in the Statement of Policy suggests the need to examine a more structured and less costly approach to providing medications to patients who, in their physicians' judgments, have requirements, both medical and financial, that cannot be fulfilled by the usual pathways. Several alternatives have been considered and implemented at other leading academic medical centers in the past several years.

In order to consider these alternatives, a representative, multidisciplinary Working Group, composed primarily of practitioners, has been appointed by UPMC and charged with the responsibility to examine this multifaceted issue and to propose a revised Drug or Device Samples section to this policy, with a goal of implementing a comprehensive policy regarding samples to be effective February 15, 2008. This Working Group will determine whether

⁶ This samples policy addresses only samples of prescription drugs or devices. Samples of consumer products (such as contact lens solution, toothbrushes, and toothpaste) may be made available to patients on an equal basis, with no product favored over another, in appropriate cases.

⁷ This amount reflects the wholesale cost of the samples, which likely substantially underestimates the real cost of producing and distributing samples.

alternative methods (such as vouchers or pharmacy-stocked sample cabinets) are feasible and can meet legitimate needs in those cases where use of samples may be justified.⁸

4. Site Access

As charitable institutions dedicated to advancing the public interest, the SOHS and UPMC should not allow use of their facilities or other resources for marketing activities by Industry. The University and UPMC always reserve the right to refuse access to their facilities or to limit activities by Industry representatives consistent with their non-profit mission. However, interaction with representatives of Industry is appropriate as it relates to exchange of scientifically valid information and other data, interactions designed to enhance continuity of care for specific patients or patient populations, as well as training intended to advance healthcare and scientific investigation.⁹ To balance these interests, UPMC's Supply Chain Management, and the University's Purchasing departments will develop a registry to assist in the management of site access by Industry representatives for appropriate purposes. Sales or marketing representatives of Industry may access SOHS or UPMC facilities only if the company with which they are associated has registered with UPMC Supply Chain Management, or, where Industry representatives seek access to the School of Dental Medicine, the University's Purchasing Department, and they have been specifically invited to meet with an individual healthcare provider or a group of healthcare providers for a particular purpose.¹⁰ Individual physicians or groups of physicians or other healthcare professionals may request a presentation by or other information from a particular company through the respective purchasing/supply chain management department or other designated institutional official. UPMC Supply Chain Management will provide names of registered Industry representatives to the University upon request.

Representatives without an appointment as outlined above are not allowed to conduct business in patient care areas (inpatient or outpatient), in practitioners' office areas, or other areas of SOHS or UPMC clinical facilities.

All Industry personnel seeking sales or vendor relationships must work directly with the UPMC Supply Chain Department (or the University Purchasing Department when seeking access to the School of Dental Medicine). While in SOHS or UPMC facilities, all Industry representatives must be identified by name and current company affiliation in a manner determined by such department, as applicable.

All Industry representatives with access to University and UPMC clinical facilities and personnel must comply with institutional requirements for training in ethical standards and organizational policies and procedures.

On-campus vendor fairs intended to showcase Industry products may be permitted if approved by the appropriate (UPMC or University) supply chain/purchasing departments, but only in campus

⁸ The recommendations of this Working Group will be considered and, where accepted, formally integrated into a revised version of this policy.

⁹ In such situations, training by Industry representatives on safe use of a regulated device may be permitted, provided that the registration procedures of this section are followed.

¹⁰ Industry representatives seeking access to the School of Dental Medicine shall register with the University Purchasing Department.

buildings in which no clinical care is delivered or in which no research is conducted. Such events must comply with the “no gifts” provisions of Sections 1 and 3 of this policy. In such situations, vendors would not be permitted to distribute free samples, free meals, raffle tickets, or any other gifts to attendees.

5. Support of Continuing Education in the Health Sciences

Industry support of continuing education (“CE”) in the health sciences can provide benefit to patients by ensuring that the most current, evidence-based medical information is provided to healthcare practitioners. In order to ensure that potential for bias is minimized and that CE programs are not a guise for marketing, all CE events hosted or sponsored by the SOHS, UPMC, or University of Pittsburgh Physicians (“UPP”) must comply with the ACCME Standards for Commercial Support of Educational Programs (or other similarly rigorous, applicable standards required by other health professions), whether or not CE credit is awarded for attendance at the event. All such agreements for Industry support must be negotiated through and executed by the Center for Continuing Education in the Health Sciences (“CCEHS”), and must comply with all policies for such agreements. Any such educational program must be open on equal terms to all interested practitioners, and may not be limited to attendees selected by the company sponsor(s). Industry funding for such programming should be used to improve the quality of the education provided and should not be used to support hospitality, such as meals, social activities, etc., except at a modest level. Industry funding may not be accepted for social events that do not have an educational component. Industry funding may not be accepted to support the costs of internal department meetings or retreats (either on- or off-campus).

SOHS or UPMC facilities (clinical or non-clinical) may not be rented by or used for Industry-funded and/or directed programs, unless there is a CE agreement for Industry support that complies with the policies of the CCEHS. Dedicated marketing and training programs designed solely for sales or marketing personnel supported by Industry are prohibited.

6. Industry Sponsored Meetings or Industry Support for Off-Campus Meetings

SOHS faculty, personnel, or students or UPMC providers or staff may participate in or attend Industry-sponsored meetings, or other off-campus meetings where Industry support is provided, so long as: (a) the activity is designed to promote evidence-based clinical care and/or advance scientific research; (b) the financial support of Industry is prominently disclosed; (c) if the SOHS/UPMC representative is an attendee, Industry does not pay attendees’ travel and attendance expenses; (d) attendees do not receive gifts or other compensation for attendance; (e) meals provided are modest (i.e., the value of which is comparable to the Standard Meal Allowance as specified by the United States Internal Revenue Service) and consistent with the educational or scientific purpose of the event. In addition, if a SOHS/UPMC representative is participating as a speaker: (a) all lecture content is determined by the SOHS/UPMC speaker and reflects a balanced assessment of the current science and treatment options, and the speaker makes clear that the views expressed are the views of the speaker and not the SOHS or UPMC; (b) compensation is reasonable and limited to reimbursement of reasonable travel expenses and a modest honorarium not to exceed \$2,500 per event.

7. Industry Support for Scholarships or Fellowships or Other Support of Students, Residents, or Trainees

The SOHS and UPMC may accept Industry support for scholarships or discretionary funds to support trainee or resident travel or non-research funding support, provided that all of the following conditions are met:

- a. Industry support for scholarships and fellowships must comply with all University or UPMC requirements for such funds, including the execution of an approved budget and written gift agreement through the Medical and Health Sciences Foundation, and be maintained in an appropriate restricted account, managed at the school or department as determined by the senior vice chancellor for the health sciences. Selection of recipients of scholarships or fellowships will be completely within the sole discretion of the school in which the student or trainee is enrolled or, in the case of graduate medical education, the associate dean for graduate medical education. Written documentation of the selection process will be maintained.
- b. Industry support for other trainee activities, including travel expenses or attendance fees at conferences, must be accompanied by an appropriate written agreement and may be accepted only into a common pool of discretionary funds, which shall be maintained under the direction of the dean or department (as specified in the funding agreement) for the relevant school. Industry may not earmark contributions to fund specific recipients or to support specific expenses. Departments or divisions may apply to use monies from this pool to pay for reasonable travel and tuition expenses for residents, students, or other trainees to attend conferences or training that have legitimate educational merit. Attendees must be selected by the department based upon merit and/or financial need, with documentation of the selection process provided with the request. Approval of particular requests shall be at the discretion of the dean.

8. Frequent Speaker Arrangements (Speakers Bureaus) and Ghostwriting

While one of the most common ways for the SOHS and UPMC to disseminate new knowledge is through lectures, “speakers bureaus” sponsored by Industry may serve as little more than an extension of the marketing department of the companies that support the programming. Before committing to being a speaker at an Industry-sponsored event, careful consideration should be given to determine whether the event meets the criteria set forth in Section 6 of this policy, relating to Industry Sponsored Meetings. SOHS or UPMC personnel may not participate in, or receive compensation for, talks given through a speakers bureau or similar frequent speaker arrangements if: (a) the events do not meet the criteria of Section 6; *or* (b) if the content of the lectures given is provided by Industry or is subject to *any* form of prior approval by either representatives of Industry or event planners contracted by Industry; *or* (c) the content of the presentation is not based on the best available scientific evidence; *or* (d) the company selects the individuals who may attend or provides any honorarium or gifts to the attendees.

Under no circumstances may SOHS and/or UPMC personnel be listed as co-authors on papers ghostwritten by Industry representatives. In addition, SOHS and/or UPMC personnel should always be responsible for the content of any papers or talks that they give, including the content of slides.

Speaking relationships with company or company event planners are subject to review and approval of the participant’s administrator, department chair, or dean as delineated in Section 2, Consulting Relationships.

9. Other Industry Support for Research

The SOHS, through the Office of Research, and UPMC, through the UPMC Office of Contracts and Grants, have established policies and contract forms to permit Industry support of basic and clinical research in a manner consistent with the non-profit mission of the University and UPMC. True philanthropic gifts from Industry may be accepted through the Medical and Health Sciences Foundation or through the appropriate UPMC hospital foundation.

D. Reporting and Enforcement

SOHS and UPMC personnel shall report their outside relationships with Industry using the combined Conflict of Interest Superform, available online at <http://coi.hs.pitt.edu>; at least annually and more often as needed to disclose new relationships. Alleged violations of this policy within the SOHS shall be investigated by the University's Conflict of Interest Office. Those within UPMC shall be investigated by the CCEHS. Suspected violations of this policy shall be referred to the individual's dean and department chair (in the case of the SOHS personnel), or to the individual's immediate supervisor (in the case of UPMC personnel), or both (in the case of persons with dual status), who shall determine what actions, if any, shall be taken. The UPMC Ethics and Compliance Office shall also be notified of suspected violations by UPMC personnel. Violations of this policy by either UPMC or University employees may result in the following actions (singly or in any combination), depending upon the seriousness of the violation, whether the violation is a first or repeat offense, and whether the violator knowingly violated the policy or attempted to hide the violation:

1. Counseling of the individual involved;
2. Written reprimand, entered into the violator's employment or faculty record;
3. Banning the violator from any further outside engagements for a period of time;
4. Requiring that the violator return any monies received from the improper outside relationship;
5. Requiring the violator to complete additional training on conflict of interest;
6. Removing the violator from supervision of trainees or students;
7. Revoking the violator's UPMC hospital privileges;
8. Fines;
9. Termination for cause.

Any disciplinary action taken hereunder shall follow the established procedures of the University and/or UPMC.

Industry representatives who violate this policy may be subject to penalties outlined in UPMC Guidelines for Purchasing Policy No. MM-0300, or other applicable University or UPMC policies, as well as other actions or sanctions imposed at the discretion of the President of UPMC or the senior vice chancellor for the health sciences. Such penalties include the following:

Violation of any of the above procedures by representatives shall result in disciplinary action which may include but shall not be limited to the following:

1. First violation: Verbal and written warning to representative; written notification to district manager or representative's supervisor.

2. Second violation: Suspension of representative and all other company sales/marketing representatives from the UPMC and/or SOHS for six months.
3. Third violation: Suspension of representative and all other sales and marketing representatives of the company from the UPMC and/or SOHS for one year or more. A review of multi-source products obtained from the company will be conducted.

Representatives found trespassing as defined in this policy will be escorted from the premises and their companies notified as appropriate.

University of Pittsburgh Medical Center

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