A Policy to Guide Behavior and Relationships with Medical Industry at the University of Kentucky

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I. Introduction

Interactions between the healthcare industry and the professions of medicine, pharmacy, dentistry, nursing, health sciences and public health, and in particular Academic Medical Centers (AMCs), have grown enormously in the last forty years. At the same time the stature of healthcare professionals in the view of society as a whole has diminished. These developments are partly interrelated. Certain interactions between the profession and Industry have been particularly troublesome to the public and to scholars of this topic including provision of gifts and meals to medical staffs, provision of free drug samples for patient distribution, sponsorship of continuing professional education (CE) and research and payment for attendance at meetings and for consulting.

Although AMCs and healthcare industries are mutually dependent on one another to improve public health, an effective and principled partnership between AMCs and various healthcare industries is critical for the welfare of both institutions and for future improvement in health care. Thus, these relationships must be preserved, encouraged and even strengthened. However, the relationships must be conducted in a way that is principled and that upholds public trust (AAMC-TF p vii and 25).[1] We must assure that these relationships are ethical and compatible with the concept of professionalism.

In 2006 Brennan and his colleagues, and in 2008 the Association of American Medical Colleges (AAMC), identified some of the problem areas and challenged AMCs to reassess their practices and establish strong guidelines for these interactions. We believe that these recommendations of the AAMC are correct and achievable. If we wish to improve our image and sustain our status in the eyes of society, the public and our patients, we must demonstrate exemplary behaviors and eliminate even the appearance of conflict of interest. To meet these objectives we have developed these guidelines to guide the behavior of University Healthcare-Related members as they relate to Industry.

It is particularly germane that AMCs provide leadership in this activity because medical, dental, pharmacy, nursing, health science and public health schools and Teaching Hospitals provide the learning environment for future practitioners in a critical and formative phase of their careers. AMCs also have special responsibilities to create and foster learning and work environments that instill professional values, norms and expectations. (Levine, 2008) Habits learned early in one's career are likely to be followed thereafter. Also, AMCs are looked upon as leaders for the whole profession.

The University of Kentucky acknowledges the vital importance of and encourages the establishment and maintenance of principled relations, communications and interactions between University Healthcare-Related members and the healthcare industry that preserves professionalism and minimizes opportunities for actual or perceived conflicts of interest, and restores public confidence in both entities.

II. Recent History of Interest in This Problem

On January 25, 2006, Brennan and his colleagues (JAMA 2006; 295: (4): 429-33) published a provocative and challenging article in which they highlighted health industry practices that create conflicts of interest and proposed a policy of more stringent regulations for academic medical centers in an effort to minimize such conflicts. (See Appendix B.) Problematic interactions identified by them included:

(1) Gifts
(2) Payment for attendance at lectures and conferences
(3) Provision of CE for no fee
(4) Payment for time while attending meetings
(5) Payment for travel to meetings, or scholarships to attend meetings
(6) Payment for participation in speakers bureaus
(7) Provision of ghostwriting services
(8) Provision of pharmaceutical samples
(9) Grants for research projects
(10) Payment for consulting relationships

In his statement in the February 2006 edition of the Association of American Medical Colleges (AAMC) Reporter, then AAMC president Jordan Cohen (who was also a co-author on the Brennan paper) enthusiastically endorsed the more stringent regulations governing behavior for members of AMCs (for purposes of this document, such members include faculty, staff, students, and house officers of the AMC). Since that time a number of medical centers have adopted such stringent policies including Stanford, Yale, University of Pennsylvania, University of Pittsburgh, University of California at Davis, University of Michigan, Boston University, and most recently Harvard University and Johns Hopkins University. Other organizations are following, according to the American Medical Student Association (AMSA) Pharmfree Scorecard that has identified at least 28 AMCs that have adopted strong policies by the AMSA definitions (www.amsascorecard.org).

In 2006 the AAMC, embracing the obligation of the profession to manage through self-regulation all real and perceived conflict of interest, appointed a special "Task Force on Industry Funding of Medical Education" to develop consensus-generated principles to guide medical schools and teaching hospitals in developing policies and procedures to manage and guide relationships with medical industry. In April 2008, that Task Force submitted its report and recommendations, which were adopted by the AAMC Executive Council at their June 18-19, 2008, meeting (http://www.aamc.org/ newsroom/pressrel/2008/080619.htm). (These recommendations are hereafter referred to as the "AAMC Task Force" or the abbreviation "AAMC-TF"- See Appendix C and on the Internet at www.aamc.org/industryfunding.)

While acknowledging that effective partnership between Industry and AMCs is critical to the benefit of medicine and patients, it was noted that medical schools and teaching hospitals were becoming increasingly dependent on Industry support, raising concerns about <u>real</u> and <u>perceived</u> conflicts of interest and inappropriate influence of objectivity and integrity. A robust body of psychological evidence and an emerging body of neurological evidence were identified that indicates the effect of interpersonal relationships and gifts on recipients' choices and decisions, and this has engendered public skepticism (AAMC-TF p 1).

They posit that AMCs have a special responsibility for teaching professionalism, ethical values and ethical practice. They also emphasized that deeds and actions often have greater impact than words on students and house officers and the public.

The AAMC Task Force summarized the problems and issues, provided guidelines and suggestions and urged all academic medical centers to accelerate their adoption of policies that better manage, and when necessary, prohibit, academic-Industry interactions that can inherently create conflict of interest and undermine standards of professionalism.

Besides the actions of the AAMC, other activity has occurred during the past year that has drawn attention to problematic relations between the healthcare professions and Industry. These have been summarized by a "White Paper" produced by McDermott, Will & Emory on July 15, 2008- see http://www.mwe.com/info/news/wp0708b.htm:

1. The Physician Payment Sunshine Act (Senate bill # 2029 and House bill # 5605) was introduced by Senator Charles Grassley and by Congressman DeFazio.
2. At least one major pharmaceutical company (Pfizer) has approved plans to stop providing direct financial support for CE provided by commercial medical education companies.
3. The Accreditation Council for Continuing Medical Education (ACCME) has issued an information and call-for-comment document regarding a ban of all commercial support of CE.
4. The AMA Council on Ethical and Judicial Affairs (CEJA report # 1-A-08) has called on physicians and institutions to stop accepting Industry funding of professional education activity (Levine, 2008). [See discussion of this proposal by AS Relman (2008)]
5. The Pharmaceutical Research and Manufacturers Association of America (PhRMA) issued in July 2008 a revision of their Code on Interactions with Healthcare Professionals that went into effect on January 1 2009. (See Appendix D.)
6. State Attorney Generals have been particularly aggressive in challenging pharmaceutical company behavior and have extracted significant monetary settlements.

III. How These Guidelines Were Developed

After the Brennan paper was published, the UK HealthCare Pharmacy and Therapeutics (P&T) Committee began to examine those issues that only related to the medical staff and the pharmaceutical industry, and reached a consensus on a number of recommendations. In May 2007, these were forwarded to the Executive Vice President for Health Affairs.

In the fall of 2007, the Dean of the College of Medicine, at the request of the Executive Vice President for Health Affairs, formed a Work Group of people from all areas of the academic medical center (including all six colleges, clinicians, researchers, nurses, pharmacists, and medical students; see Appendix A for list of members) to review current guidelines and develop new guidelines based on the aforementioned work of others and the opinions of members of this Work Group. This effort was strongly influenced by the Brennan report and, most recently, the AAMC Task Force. Other important resources included The University of Pittsburgh Policy of November 12, 2007 (http://www.coi.pitt.edu/IndustryRelationships/policy.htm);

the revised Code on Interactions with Heath Care Professionals, PhRMA July 2008 (http://www.phrma.org/files/PhRMA%20Marketing%20Code%202008.pdf); the University of Kentucky Code of Conduct Addendum-Clinical Compliance Policy (http://mcsharepoint/evpha/ops/cc/default.aspx); and medical literature. (See bibliography appended.)

After reaching a consensus, this document was written by a "Writing subgroup" (See Appendix A for list of members) and then presented to the entire Work Group for their modification and approval.

After presentation to the College of Medicine Council of Chairs and Center Directors, it will be circulated and discussed at several open meetings before adoption.

IV. The Guidelines

A. Introduction

1. To Whom These Guidelines Apply

These guidelines apply to all University members acting on behalf of the University of Kentucky with respect to any of its Healthcare-Related activities; such members are referred to in these Guidelines as "University Healthcare-Related members."

"University members" is defined in Part I.D.2 of the Governing Regulations, to include "trustees, executive officers, faculty, staff, and other individuals employed by the University, those using University resources or facilities, and volunteers and representatives acting as agents of the University."

The Healthcare-Related activities of the University of Kentucky include the healthcare delivery, clinical, and academic programs of the University of Kentucky Colleges of Medicine, Dentistry, Nursing, Pharmacy, Health Sciences, and Public Health, their affiliated faculty practice plans, University of Kentucky Hospital, UK HealthCare Good Samaritan Hospital, UK HealthCare Ambulatory Services and related support organizations and programs. The University of Kentucky academic Healthcare-Related activities are pursued through these six colleges. The University of Kentucky healthcare delivery and clinical activities are commonly known as "UK HealthCare."

In order to avoid even the appearance of impropriety or conflict of interest, these Guidelines (and the policies and regulations that reflect the adoption of these Guidelines) apply to all faculty, staff, house officers and students involved in the University of Kentucky Healthcare-Related activities, without regard to an individual's specific job duties or function. Students within the six colleges and house officers are subject to these Guidelines, because of their involvement, or potential involvement, in clinical or healthcare activities and because of the training value for such students and house officers of compliance with regulations pertaining to the healthcare industry.

2. What Is Meant by the Term "Industry"

Industry includes the pharmaceutical, biotechnology, and medical device industries, as well as providers of hospital and clinic equipment, supplies and services. (AAMC-TF p iii)

B. Specific guidelines

1. Gifts including food and meals

Background and rationale: The provision of gifts, including those of professional or educational value such as books and equipment, food and meals is a ubiquitous practice in the Industry. Most health care professionals do not believe that their judgment and integrity are influenced by this practice. However there is little doubt as to the purpose and effectiveness of such marketing tactics. There is a robust body of psychosocial evidence and an emerging body of neurobiological evidence indicating the effects of interpersonal relationships and gifts (no matter of what value or purpose) on recipient choices and decisions (AAMC-TF p. 1). It is important to recognize that the impact of these gifts on behavior may *not be intentional on the part of the recipient* but is subconscious despite the integrity and good intentions of the recipient. This reward/decision-making circuitry in the brain operates below the level of detection and control by higher cognitive centers. Food and snacks are also considered and have the same (or greater) effect as other gifts on the recipient. The provision and acceptance of such gifts have received much attention in the press and contributed to suspicion and deterioration of the public image of the profession (AAMC-TF p. 1).

Current Policy: Part I.D.2(m) of the Governing Regulations prohibits the acceptance by a University member of gifts, benefits, rewards, both monetary and nonmonetary, and acts of hospitality if there is an implicit or explicit assumption that influence has been exchanged for the favor and otherwise based on value. The University of Kentucky Code of Conduct Addendum prohibits the acceptance of gifts or benefits that could be perceived as an attempt by a vendor to interfere with the University Healthcare-Related member's independent judgment.

Guideline #1: Gifts and Benefits:[2]

a. Gifts of any value, including drug samples for personal use, snacks and meals, printed and electronic medical books, supplies and equipment, payment for travel to and/or attendance at meetings, and participation in online Industry sponsored "CE", should not be offered by Industry and nor accepted by University Healthcare-Related members. (AAMC-TF p 4, 14)

b. This prohibition will apply to snacks and meals supplied by Industry at all on-site/on-campus medical center sponsored programs, seminars and meetings.

c. The only exception to this prohibition is food provided in connection with an accredited CE program, which is in conformity with Accreditation Council for Continuing Medical Education (ACCME) guidelines (See Appendix E) or other similar continuing education accreditation guidelines.[3] (AAMC-TF p 21)

d. University Healthcare-Related members should not accept food and drink provided by any Industry representative on any occasion on- or off-site

and whether on or off duty, unless it falls under the exception c. mentioned above.

[NB: A fundamental concept promulgated by the AAMC Taskforce is that Professionalism is a full-time characteristic and hence guidelines that guide professional conduct on-site/on-campus and during working hours, should equally apply to conduct off-site and during free time. Professionals are professionals all the time, and should act appropriately at all times. Furthermore it is irrational that behavior that is considered unprofessional in one setting or time would not be unprofessional in other settings or times. Thus throughout these guidelines, University Healthcare-Related members are expected to follow these guidelines while off-duty and off-campus.]

2. Promotion of drugs and other biologic products, devices, equipment, and other products, and site access by Industry representatives

Background and Rationale: Industry must be provided with the opportunity to introduce and promote their products to the staff of the institution for the benefit of Industry, as well as the benefit of UK HealthCare and our patients. However, there is ample evidence that Industry promotions are often biased and may not provide the best evidence on a subject. Within the environment of an academic medical center, this limitation creates the obligation for the faculty, staff and administration to develop and enforce very specific guidelines to regulate and limit, or even completely forbid, direct unsupervised contact between Industry representatives and students and house officers.

In addition, Industry representatives are often required to assist with the clinical application of a complex new device or piece of equipment. Although this may be entirely appropriate, there is a real risk that their presence could be perceived by patients and/or other personnel as a mere promotional activity. Furthermore, the quality, appropriateness, risks and liability related to the use of any of these devices remains squarely on the shoulders of the faculty and staff, and on the institution itself.

In regard to these guidelines, "Industry representatives" include all sales, marketing and 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." Industry representatives also include individuals indirectly related to Industry.

Current Policy. Section B-2 of the University of Kentucky Business Operations Manual provides that all purchasing shall be conducted in accordance with the Model Procurement Code. Further, purchases and contracts shall not be made with an employee of the University of Kentucky for any item of supply, equipment, or service, nor may an employee have any interest, directly or indirectly, in any purchase made by the University of Kentucky. Purchases for the University are made for the purpose of meeting program requirements of the various units. Hospital Policy HP01-31 provides specific guidance for Industry representatives with respect to hospital purchasing and the presence of Industry representatives within the hospital as required by The Joint Commission.

Guideline #2:

a. Current policy described above remains in full force and effect. Hospital Policy HP01-31 shall apply to UK HealthCare.

b. If Industry wishes to introduce a non-pharmaceutical surgical product or device into this institution that has not been approved by the appropriate oversight committee for general use within the University or UK HealthCare in particular, the Industry representative should contact the appropriate faculty or senior staff, (i.e. not an individual in training), to have him or her evaluate the request and, if justified and valid, present the appropriate request to the corresponding device or product evaluation and selection committee of the University or UK HealthCare. Students or house officers should never be directly approached by Industry about a product that has not yet been evaluated and approved for use in the University.

c. If Industry wishes to introduce a pharmacological and biological agent into this institution, the exact same process must be followed, and the request, if appropriate, will be presented to the P&T committee. Direct unsupervised contact between pharmaceutical representatives and students or house officers to promote a drug that has not been evaluated and approved by the P&T committee is not allowed in this institution.

d. Products, devices, and drugs not yet approved for use in the University can and should be discussed with students and house officers as part of the formal educational efforts of the corresponding departments or divisions. These discussions, however, must be initiated, designed, directed, and supervised by the appropriate senior staff or faculty. Under no circumstances should Industry dictate the content or provide paid speakers for this purpose. Unsupervised "educational lunches" for students and house officers initiated and sponsored by Industry are prohibited whether on-campus or off-campus.

e. Whenever a new product, device, or pharmacological agent is approved for general use or trial in any University Healthcare-Related activities, education and training of the appropriate faculty and staff should be organized and supervised by a University Healthcare-Related faculty or staff member. These educational/training sessions should be done in a formal and structured fashion that allows ample opportunity for discussion and critical appraisal. Students and house officers can greatly benefit from participating in this process. Industry can participate in these activities and provide educational resources, including literature, technical people, or expert users, but only with the specific and direct approval of the faculty or staff member coordinating this process.

f. Access by Industry representatives to University Healthcare-Related faculty and staff members should be limited to non-public, non-patient-care areas, and should only occur by appointment or invitation from the faculty or senior staff member. Involvement of students and house officers in such meetings is encouraged but should only occur under the direct supervision of faculty or senior staff personnel.

g. Industry representatives should register appointments they have throughout UK HealthCare.

h. When the presence of Industry representatives in patient care areas is deemed advisable and necessary, the attending physician must assume full responsibility for the Industry representative's appropriate presence and performance in the clinical area. This activity must be guided by applicable law and UK HealthCare policies governing patient privacy and confidentiality, informed consent, and quality patient care. There must be written documentation of the representative's competence and qualifications to perform whatever tasks are assigned to this individual, appropriate background checks, and there must be clear documentation that his or her presence is essential for safe and efficient patient care. Finally, as part of the informed consent process, the patient must be informed of the presence, purpose and role of the Industry representative.

i. Under the circumstances defined above in subsection h, no gifts of any value, including meals and snacks, and no promotional activities of any type, can be given or take place in association with the presence of the Industry representative in the patient-care clinical area.

j. Training and Off Site Visits by faculty and staff. On occasion UK faculty or staff may be required to travel to other locations in order to view or train on new equipment or systems that are used, intended to be used, or under consideration for purchase for use in a University Healthcare-Related activity. Such travel is only considered legitimate if the product, equipment or training cannot reasonably be brought to the University campus. The following guidelines should be observed:

   (1) All site visits must comply with the Commonwealth of Kentucky Model Procurement Code and UK Purchasing rules, and be coordinated with the UK Purchasing Division.

   (2) Generally, if the University is evaluating a product or service, the site visit should be considered an operating expense of the University area that is considering the purchase. All costs related to the site visit will be the responsibility of the University area that visits a particular location.

   (3) If the University has purchased or has agreed to purchase an item or service, and a site visit or training is included as part of the purchase agreement, it is appropriate for the vendor to pay for the travel, meals and lodging. However, entertainment associated with the travel is not appropriate and the travel, lodging, and meals must be reasonable.

3. Membership on drug, device and equipment evaluation and selection committees

Background and rationale: The potential for conflict of interest arising from any relationship between a member of a drug, device or equipment evaluation and selection

committee and Industry is obvious, and therefore, actual or appearance or perceived conflicts by the public must be guarded against.

Current Policy: Section B-2 of the University of Kentucky Business Operations Manual provides that purchases and contracts shall not be made with an employee of the University of Kentucky for any item of supply, equipment, or service, nor may an employee have any interest, directly or indirectly, in any purchase made by the University of Kentucky.

Guideline #3[4]:

a. Persons who serve on Pharmacy and Therapeutic/ Value Analysis/ Technology Assessment committees shall fully disclose all relations with Industry, without exception, at least once a year and whenever relevant changes occur. Full disclosure must include without limitation, speaker bureaus, occasional speaker engagements, stock ownership, grants or educational support received or being applied for, research involvement with any drug, device or equipment, consulting work, patents, etc., as well as immediate family member relations. Disclosure shall be made on a form developed for such purpose by the University and shall be made to the Vice President for Health Care Operations. Persons whose relations with Industry create conflicts in serving on such committees may be removed from such committees.

b. When an item is discussed in which a member has a potential conflict of interest based on a financial or research or investigational relationship with the involved Industry, the nature of the relationship shall be disclosed to the committee at that time. That individual may participate in the discussion at the discretion of the chairperson of the committee but shall excuse himself or herself from the final decision making.

4. CE activity by Industry.

Background and rationale: Industry provides support of the majority of CE currently offered in the United States (Relman 2008). Programs sponsored by Industry are biased by design, and this effect is not dispelled by disclosure of potential conflict of interest. AMCs are responsible for assuring objectivity and balanced presentations for accredited education (ACCME or other accrediting body) programs that are Industry supported.

In the ideal world AMCs should decline all financial support of CE by Industry but this does not appear to be financially feasible or practical at the present time (Relman 2008). Thus, while this practice continues, it is important to minimize actual or appearance of conflicts of interest and to separate as far as possible the donor from the recipient.

Current Policy: AR II-1.0-2 Policy of the University of Kentucky Governing Speakers From Off Campus, states:

> It is the policy of the University to encourage its administration, faculty and students to invite outside speakers to its campus. The appearance of such speakers does not imply approval or disapproval of them or of their views. They are brought to the campus because it is believed that their discussions will further the educational goals of the University.

The University will act responsibly in inviting speakers and expects its guests to act responsibly. Its policies require that no law or governing regulation of the University be violated by the speech or program. The University also requires that meetings on its campus at which off-campus speakers appear be peaceful and orderly and in no way interfere with the proper functioning of the University. Further, the University through the Office of the President may prescribe conditions for the conduct of programs at which off-campus speakers appear. These conditions may include requiring a University official or a senior faculty member to chair the program, requiring opportunity for comments and questions from the floor, or such other practices as may be necessary to preserve order and to insure an atmosphere of open exchange of ideas. In addition, the President may take appropriate action to insure that the University community is provided with a balanced exposure to divergent opinions on controversial issues.

Continuing education programs offered by the Colleges of Medicine and Pharmacy are accredited by the Accreditation Council for Continuing Medical Education and the Accreditation Council for Pharmacy Education, respectively. Accreditation Council for Continuing Medical Education standards include Standards for Commercial Support. (See Appendix E.) Accreditation Council for Pharmacy Education standards provide that, "Commercial interests cannot be accredited providers and cannot be cosponsors."

Guideline #4[5]:

a. Industry initiated and conducted (i.e., Industry sponsored) conferences, seminars and other meetings shall *not* be permitted on-campus.
b. Only properly accredited CE activities may be funded or supported by Industry, if desired, and national guidelines regarding commercial funding for CE programs must be explicitly followed in all cases. (See Appendix E.)
c. All commercial support for educational activities shall be requested by, and given to, a College, Department, Division, or other similar group, and not to any one specific individual.
d. Other than properly accredited (ACCME or other) CE activities, there shall be no direct sponsorship of institutionally initiated and conducted conferences and meetings.
e. Under no circumstances shall Industry representatives be allowed to select the topic or the speaker for any educational activity.
f. University Healthcare-Related members are discouraged from attending Industry initiated and conducted non- accredited off-campus meetings that are advertised as CE.

5. Support for scholarships, fellowships or other support of students or house officers by Industry

Background and rationale: In an ideal world, AMCs should decline all financial support from Industry for medical education, including graduate medical education (GME). This may not be economically feasible at the present time. Central institutional administration and oversight of scholarships and other educational funds (for travel, books and supplies) helps prevent one-on-one relationship between donor and recipient and perception that these are direct gifts.

Guideline #5[6]: (AAMC-TF p. 21)

a. Industry support for student and house officer activities, including travel expenses or attendance fees at carefully selected educational 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 at the college or department as determined by the dean. 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 students or house officers to attend conferences or training that have legitimate educational merit. Attendees must be selected by the department/division based upon merit and/or financial need, with documentation of the selection process provided with the request. Conferences that qualify as a "carefully selected educational conference" are in general terms defined by the major educational, scientific, or policy-making meetings of national, regional, or specialty medical associations. Approval of particular requests shall be at the discretion of the dean.

b. Industry support for student and house officer training, tuition , stipend and benefits must comply with all University and UK HealthCare requirements for such funds (policy to be developed), including the execution of an approved budget and written gift agreement and be maintained in an appropriate restricted account, managed at the college or department as determined by the dean. Selection of recipients of scholarships, fellowships or tuition support will be within the discretion of the college in which the student is enrolled or, in the case of house officers, the dean.

c. No quid pro quo shall be involved.

d. These guidelines do not apply to formal research grants supported by Industry.

6. Consultation work for Industry

Background and rationale: It is beneficial for Industry, the University, and the public health for University Healthcare-Related faculty and staff to provide consultation and guidance and learned advice to Industry. Care must be taken not to interfere with productive and ethical collaboration. However, such relationships must be carefully scrutinized and approved and follow university guidelines. Serving as an occasional speaker at an industry sponsored educational program is considered as consulting work. (See item 10 below.)

Current Policy: AR II-1.1-1, Consulting and Other Overload Employment sets out the parameters including the approval process for faculty to engage in external consulting. Faculty members are required to obtain approval from their dean before entering into any consulting arrangement. Human Resources Policy and Procedure Number 18.0: Outside Employment sets out the parameters for staff to engage in external employment, including a recommendation that the staff employee inform his or her supervisor of the outside employment. Both the administrative regulation and the Human Resources Policy and Procedure prohibit faculty and staff from engaging in consulting or outside employment that gives rise to a conflict of interest

with respect to their relationship with the University. The University of Kentucky Code of Conduct Addendum, the Clinical Enterprise Compliance Policy and Administrative Regulations governing faculty practice plans set out additional limitations on consulting arrangements for University Healthcare-Related members to ensure compliance with applicable federal law.

Guideline #6[7]:

a. All University Healthcare-Related members will abide by AR II-1.1-1, Consulting and Other Overload Employment, Human Resources Policy and Procedure Number 18.0 Outside Employment, the University of Kentucky Code of Conduct Addendum, the Clinical Enterprise Compliance Policy and Administrative Regulations governing faculty practice plans with respect to all outside employment and consulting arrangements. Serving as an occasional speaker at industry sponsored programs is considered consulting. (See item 10 below.)

7. Participation in Industry sponsored research

Background and rationale: An essential role of the University is to collaborate with Industry in medical research and these activities must be cultivated and encouraged. However, the academic investigator must maintain academic freedom and have an essential role in design of the experiment and maintain control of the results and have freedom of publication. Faculty must receive guidance and oversight in developing these collaborations.

Guideline #7:

a. University Healthcare-Related members who participate in Industry sponsored research must abide by the University of Kentucky Research Conflict of Interest and Financial Disclosure Policy.

8. Publication of research initiated, supported, or sponsored by Industry

Background and rationale: University Healthcare-Related members, who author or co-author publications related to research sponsored by or initiated by Industry, have a responsibility to their readers to assure accuracy and to reveal any potential conflicts of interest. Therefore, the authors must comply with the following guidelines, some of which have been promulgated by the editors of leading medical journals. (See Davidson, et al (NEJM 2001, 345:825.)

Guideline #8:

a. University Healthcare-Related members who author or co-author publications related to research sponsored by or initiated by Industry, must comply with the following:

(1) Full disclosure of any possible conflicts of interest on the part of all authors.
(2) Full disclosure of sponsor's role in the study and writing of the paper.
(3) The author(s) must have substantial say in trial design.
(4) The author(s) must have access to raw data.

(5) The author(s) must be responsible for data analysis and interpretation.
(6) The author(s) must retain the right to publish results without consent or prolonged review by the sponsor.

9. Ghostwriting

Background and rationale: "Ghostwriting" refers to the practice in which someone else has provided written material that is then credited or attributed to someone other than the original writer. In this document, it refers to a University Healthcare-Related member adding his or her name to a manuscript that was conceived, designed, and mainly written by someone else, (often an Industry representative or a proprietary research organization under contract with Industry) which the University Healthcare-Related member played no essential role in its development and writing. It excludes manuscripts written by others within of the University Healthcare-Related member's department/division (i.e. faculty, staff, fellows, residents, students) for whom the University Healthcare-Related member has a supervisory role and played an advisory role in the development of the manuscript, carefully scrutinized the content and assured the accuracy of said manuscript. It also does not apply to the transparent writing in collaboration with an Industry investigator, medical writer or technical expert.

Guideline #9[8]:

a. University Healthcare-Related members shall not allow their names to be listed on papers that were ghostwritten as defined above.
b. The source or author of all content of an article must be documented in all published manuscripts. Although criteria for authorship vary, authorship qualification should be based on meeting the following criteria:

(1) The person substantially contributes to conception and design, or acquisition of data, or analysis and interpretation of data;
(2) The person drafts the article or revises it critically for important intellectual content;
(3) The person approves final version to be published; and
(4) The person agrees to be named as an author.

10. Participating as a speaker at Industry sponsored non accredited "educational" programs and in Industry "speakers bureaus"

Background and rationale: There are two ways in which a University Healthcare-Related member might participate in an Industry sponsored non-accredited program. One is as a member of an Industry speakers bureau, and the other is as an occasional invited sponsored speaker.

The new PhRMA code on Interactions with Healthcare Professionals (July 2008) clearly defines and describes what is meant by health care professionals who participate in an Industry sponsored speakers program (identified in this document as "speakers bureaus"). (See item 7, pages 9-10 of the new PhRMA code.) These health care professionals participate in order to help educate and inform other health care professionals about the benefits, risks and appropriate uses of company medicines and participate in such external promotional programs on behalf of the company. The company selects the speakers and provides them with training on the

company's products and compliance with FDA regulations and assures that the speakers provide a valuable service to the company. The document goes on to state that these programs are distinct from CE programs, and that these speakers should be clear about this distinction. The speakers must make clear in their presentations and material that they are sponsored by a company and are presenting on behalf of the company.

Thus, speaker bureaus are an extension of Industry's marketing apparatus (Brennan, 2006). By participating, University Healthcare-Related members are contributing their reputation and the credibility of the University to the marketing of a product by a company. These programs are often biased toward the marketing of a particular product and are not usually designed to provide a balanced and critical appraisal of the therapeutic options and limitations despite the best intention of the participating University Healthcare-Related members. For these reasons University Healthcare-Related members should not participate in Industry speakers bureaus even if such programs are FDA-regulated. This prohibition obviously does not apply to speaking at accredited programs that may receive Industry support but only as permitted by the guidelines of the accreditation body.

Participating as an occasional sponsored speaker a non-accredited Industry sponsored FDA regulated educational program when the content is not controlled by Industry is less problematic and may have benefits to the medical community if closely regulated.

Guideline #10[9]:

a. University Healthcare-Related members should not participate in Industry "speakers bureaus" (as defined above).
b. University Healthcare-Related members may participate as occasional sponsored speakers in non- accredited Industry sponsored FDA-regulated "educational" programs (AAMC-TF p 20), only if the following criteria are satisfied:
    (1) He or she should be convinced that the activity is designed to promote evidence-based, unbiased clinical care and/or advances in scientific research.
    (2) The financial support of Industry should be prominently disclosed.
    (3) The lecture content and slides should be determined by the University Healthcare-Related member and reflect a balanced assessment of the current science and treatment options.
    (4) The University Healthcare-Related member should make clear that the views expressed are those of the speaker and not those of the University or UK HealthCare.
    (5) Compensation for travel, expenses and honorarium may not exceed the fair market value of the services provided and must comply with the UK Guidelines for such compensation.
    (6) Such activity shall be considered consulting and must comply with the guidelines applicable to consulting described above (Section 6).

11. Provision of drug samples for patients by Industry

Background and rationale: The receipt of drug samples from Industry by practitioners to give to their patients raises many troubling issues including:

- Bypassing the evaluation, selection and distribution system of the pharmacy and the P&T committee.
- Potential for establishing of biased reciprocal relationships (AAMC-TF p.15).
- May unduly influence physician prescribing habits.
- Introduces patients to, and encourage them to rely on, newer and often more expensive agents that may not be better or may even be more dangerous than alternatives.
- Provides Industry with an opportunity for "gifting" the medical staff.
- Improper drug storage and control procedures while under the control the pharmaceutical representative or physician leading to diminished potency and the potential for diversion and inappropriate access.
- Lack of patient labeling/instructions resulting in an increased risk of medication errors.
- Lack of documentation of care and incomplete medical and pharmacy records.

Provision of drug samples does have some positive benefits in that it provides indigent patients with immediate access to drug therapy, although recent research has indicated that drug samples are more likely to be distributed to the wealthy and insured (Cutrona SL Am J Pub Hlth 2008;98/2:284-9).

Guideline #11[10]:

a. UK HealthCare should move toward a voucher model, for providing access to free pharmaceuticals when and where feasible.
b. If drug samples are utilized, they must be adequately controlled and secured, with dispensing and patient care documented according to established procedures meeting professional standards. The current hospital policy is: PH-11-11: Pharmaceutical Samples.
c. Some exceptions may have to be made for drugs and devices required for patient education and training in the ambulatory setting (i.e. some inhalers, nebulizers, insulin, etc.) and for ambulatory care locations where University pharmacy services are not available.
d. When practitioners do dispense donated drug samples to patients, the practitioner should explain to the patient why that particular product is available and, when applicable, inform the patient concerning the availability of cheaper and perhaps safer alternative agents.
e. These guidelines regarding pharmaceutical samples should also be followed in regard to samples of medical supplies and devices.

V. Administration, management, compliance, enforcement and disciplinary action

These Guidelines are intended to encourage ethical and professional behavior by all University Healthcare-Related members. The Guidelines also are a means for demonstrating our concern with potential or actual conflicts of interest and our methods for avoiding such conflicts. A primary objective is to change behaviors through education and training, as opposed to punishment. This objective must not be construed to mean that appropriate discipline should not or may not be applied in instances of noncompliance.

The amended and restated University of Kentucky Code of Conduct Addendum reflecting these Guidelines, together with other regulations, policies and procedures described in this document constitute the official regulations, policies, procedures and code of conduct of the University and UK HealthCare.

Education and training will be provided by publication of these Guidelines in Staff and Faculty handbooks and on appropriate University and UK HealthCare websites.

Representations of compliance with these Guidelines, at the Department level, will be included in the Executive Summary Annual Compliance Report prepared by each Department and College. This method of confirming compliance is consistent with the UK HealthCare approach of 'delegated accountability' for specific areas of compliance.

Another method for complying with these Guidelines will be to audit the behavior of University Healthcare-Related members. Remediation of conflict situations will be promptly addressed.

In addition to the foregoing, UK HealthCare shall establish an Advisory Committee on Industry Relations. The charter for that committee will be created at its initial meeting. The Advisory Committee shall consist of Faculty and Staff from clinical and research areas. At a minimum, the Committee will:

- Periodically review and make recommendations for revisions to these Guidelines;
- Review audits conducted by, or at the direction of, the Advisory Committee;
- Review complaints of potential violations of these Guidelines, and:
    - Discuss each matter with the individual(s) involved;
    - If a violation of these Guidelines is confirmed, explain the situation to the violator and advise how to prevent future violations;
    - Inform appropriate supervisory personnel of the violation; and
    - Any violation would be handled through the respective area and Human Resources in accordance with UK's "Progressive steps of discipline." These are addressed in published UK Policies: Corrective Action: http://www.uky.edu/HR/policies/hrpp062.html and Separation of Employment: http://www.uky.edu/HR/policies/hrpp012.html

VI. Implementation

A. Annual Reporting

Background and rationale: Faculty and staff are presently required to make certain financial disclosures relating to research activities. Faculty members are also required to obtain prior approval for consulting arrangements, and staff are required to make certain disclosures relating to outside employment. Participants in faculty practice plans are required to report, and in most cases, tender to the plan, all professional income. Compliance with these guidelines anticipates annual reporting by University Healthcare-Related faculty and staff members.

Annual reporting under these guidelines will include disclosure of relationships with Industry, including research support, participation in Industry sponsored or supported educational or informational programs, consulting engagements, Industry board and advisory board memberships and any other relationship with Industry that may raise a conflict of interest.

The annual disclosure requirements must be coordinated throughout the University to ensure that meaningful information is gathered and that the reporting requirement does not create an undue burden on faculty or staff.

B. Engagement of Industry

Background and rationale: It is the role of AMCs to police their own members. On the other hand we also should seek the cooperation and support of Industry in facilitating compliance of University Healthcare-Related members with our guidelines. To accomplish these goals, the University will initiate dialogue with Industry alerting them to our guidelines and asking them to respect our guidelines and cooperate by voluntarily discontinuing those practices that in our opinion compromise professionalism and principled relations and erode public trust (AAMC-TF p iii). Specifically Industry will be asked to discontinue:

- Provision of gifts of any value, including snacks and meals to University Healthcare-Related members both on and off-campus.
- Sponsoring off-campus non-accredited forums designed to market their products.
- Soliciting University Healthcare-Related members to serve on speakers bureaus.
- Marketing drugs and devices to University Healthcare-Related members that have not been approved for use or evaluation within the University or UK HealthCare by the appropriate committees.
- Providing drug samples directly to physicians for distribution to patients. Instead they will be asked to cooperate with mechanisms developed for provision of drug samples as outlined in item IV.B.11 above.

C. Development of education programs on relations between University Healthcare-Related members and Industry

Background and rationale: Essential to implementing these guidelines and achieving support and compliance from University Healthcare-Related members is providing adequate education regarding the rationale for these guidelines. This will be accomplished by developing a curriculum and forums for communicating with University Healthcare-Related members. However, in developing this curriculum, the University recognizes that the "Hidden Curriculum" (how the institution and its members behave) has more impact than any document or formal educational program. (AAMC-TF p 10) Therefore our emphasis will be to provide a culture and learning environment of institutional and personal behavior that teaches good practices and professionalism by example.

To accomplish this goal, the University will develop educational programs directed at students, house officers, faculty, including volunteer faculty, and staff regarding proper professional and ethical relations between University Healthcare-Related members and Industry. Among other items the curriculum will include at least:

a. Reinforce adoption of high individual standards, norms and behavior (AAMC-TF p 11).
b. The challenges to professionalism presented by certain interactions with Industry including the subconscious biases introduced by gifts (AAMC-TF p 11).

c. The marketing tactics employed by Industry in promoting their products.
d. The impact of Industry involvement on the quality of medical literature.
e. How to evaluate critically the literature and new therapeutic options (AAMC-TF p 11).
f. How to avoid inadvertent bias in using and prescribing drugs, devices, and evaluating equipment.
g. How to recognize and deal with potential conflicts of interest.

Separate and dedicated programs directed at students, house officers, faculty, including volunteer faculty, and staff, will be developed by the appropriate organizations (i.e. Medicine, Dentistry, Nursing, and Pharmacy schools' Curriculum Committees, GME office, Medical staff office, UK Chandler Hospital) to meet the particular needs of each group. In regard to Medical Students, this educational program should be initiated during the first year before the students come in contact with clinical practice environments. Formats will include lectures and seminars, publications and online postings.[11]

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VIII. Endnotes

[1] The designation AAMC-TF refers to the report of the AAMC Task Force on Industry Funding for Medical Education, April 2008 (www.aamc.org/industryfunding).

[2] These guidelines regarding gifts follow the recommendations of the AAMC Task Force (Chap 2, item B, page 14; item I, page 21; and item J, page 22).

[3] It should be understood that throughout this document that although the terms CME and AAMC specifically refer to Continuing Medical Education of physicians and the oversight of the Accreditation Council for Continuing Medical Education, they are used in this document to refer to continuing professional education in all of the health care disciplines, and the organizations that provide oversight of these activities.

[4] These guidelines on committee membership follow the recommendations of the AAMC Task Force (Chap 2, item L, page 22).

[5] These guidelines on Industry support of CME follow the recommendations of the AAMC Task Force (Chap 2, item F, page 19).

[6] These guidelines on Industry support of academic programs follow the recommendations of the AAMC Task Force (Chap 2, item H, page 21).

[7] These guidelines regarding consultation arrangements follow the recommendations of the AAMC Task Force (Chap 2, item M, page 23).

[8] These guidelines on ghostwriting follow the recommendations of the AAMC Task Force (Chap 2, item K, page 22).

[9] These guidelines on participating in Industry supported programs and speakers bureaus follow the recommendations of the AAMC Task Force (Chap 2, item G, pages 20-21).

[10] These guidelines on drug samples follow the recommendations of the AAMC Task Force (Chap 2, item D, pages 15-16).

[11] Some suggestions for developing such a curriculum for medical students can be found in Report X Contemporary issues in medicine: Education in safe and effective prescribing practices. The Medical School Objectives Project. Association of American Medical Colleges. July 2008.

IX. Appendices

A. List of membership of Drug/Vender Work Group

- Armitstead, John*;
- Balke, C. William;
- Berger, Roland*;
- Brown, Ryan R*;
- Cheever, Todd R;
- Clark, Murray;
- Dawson, Terri;
- Giordani, Mauro;
- Hall, Edward D;
- Hessel II, Eugene A*;
- Higdon, Courtney;
- Lofgren, Richard;
- Mcdowell, Susan*;
- Melgar, Sergio;
- Olges, Jennifer R*;
- Pearce, Kevin;
- Perman, Jay A*;
- Rapp, Doris A;
- Reister, Paul;
- Robinson, Fonda G;
- Sargent, Jean;
- Short, R Brett*;
- Steiner, John E*

*Writing subcommittee

B. Summary of Recommendation of Brennan et al (JAMA January 2006)

(1) All gifts (zero dollar limit), free meals, payment for travel to or time at meetings, and payment for participation in online CME from drug and medical device companies to physicians should be prohibited.

(2) The direct provision of pharmaceutical samples to physicians should be prohibited and replaced by a system of vouchers for low-income patients or other arrangements that distance the company and its products from the physician.

(3) Hospital and medical group formulary committees and committees overseeing the purchases of medical devices should exclude physicians (and all health care professionals) with financial relationships with drug manufacturers, including those who receive any gift, inducement, grant or contract.

(4) Manufacturers should not be permitted to provide direct support directly or indirectly through a subsidiary agency to any ACCME-accredited program. Manufacturers wishing to support education for medical students, residents and/or practicing physicians should contribute to a central repository (i.e., a designated office at an AMC) that in turn would disburse funds to ACCME-approved programs.

(5) Pharmaceutical and device manufacturers interested in having faculty or fellows attend meetings should provide grants to a central office at the AMC. That office could then disburse funds to faculty and training program directors.

(6) Faculty at AMCs should not serve as members of speakers bureaus for pharmaceutical or device manufacturers.

(7) Faculty should be prohibited from publishing articles and editorials that are ghostwritten by industry employees.

(8) Consulting with or accepting research support from industry should not be prohibited. However … consulting or honoraria for speaking should always take place with an explicit contract with specific deliverables.

(9) AMCs should be able to accept grants for general support of research from pharmaceutical and device companies.

(10) Medical schools must be prepared to monitor compliance and enforce (these rules).

C. Summary of AAMC Task Force Recommendations, April 2008 (Executive summary)

Report of the AAMC Task Force on Industry Funding
of Medical Education to the AAMC Executive Council

AAMC

Executive Summary[1]

An effective and principled partnership between academic medical centers and various health industries is critical in order to realize fully the benefits of biomedical research and ensure continued advances in the prevention, diagnosis, and treatment of disease. Appropriate management of this partnership by both academic medical centers and industry is crucial to ensure that it remains principled, thereby sustaining public trust in the proposition that both partners are fundamentally dedicated to the welfare of patients and the improvement of public health.

Over recent decades, medical schools and teaching hospitals have become increasingly dependent on industry support of their core educational missions. This reliance raises concerns because such support, including gifts, can influence the objectivity and integrity of academic teaching, learning, and practice, thereby calling into question the commitment of academia and industry together to promote the public's interest by fostering the most cost-effective, evidence-based medical care possible.

The Association of American Medical Colleges (AAMC) embraces the obligation of the profession to manage, through effective self-regulation, all real or perceived conflicts of interest. Accordingly, in 2006 AAMC charged a special Task Force on Industry Funding of Medical Education (hereafter referred to as Task Force) with forging consensus principles to guide the AAMC and the leaders of medical schools and teaching hospitals in developing policies and procedures to manage industry gifting practices and financial support of their programs of medical education for students, trainees, faculty, and community physicians. This report is the product of the Task Force's efforts.

The Report acknowledges the new policy directions being implemented in many medical schools and teaching hospitals to address industry support of medical education, and it urges all academic medical centers to accelerate their adoption of policies that better manage, and when necessary, prohibit, academic-industry interactions that can inherently create conflicts of interest and undermine standards of professionalism. Although the charge to the Task Force was focused on funding from the pharmaceutical and device industries, institutional policies on conflicts of interest should be comprehensive and encompass providers of equipment and services as well. Concomitantly, industry should voluntarily discontinue those practices that compromise professionalism as well as public trust.

[1] The Task Force report and recommendations have been approved unconditionally by all Task Force members, with the exception of Jeffrey B. Kindler (Pfizer), Kevin Sharer (Amgen), and Sidney Taurel (Lilly). Mr. Sharer supports the "explicit recommendations" of the Task Force, but "is not in a position to endorse the text" of the report. Mr. Sharer further states that "It is understandable that industry and academe will not agree completely on the final wording of any report given our differing roles in health care." Mr. Kindler and Mr. Taurel support all but one of the Task Force recommendations, noting that "We do so without endorsing all of the supporting arguments used in the body of the report." The recommendation of concern, in Chapter 2 under the heading of "Industry-Sponsored Programs," actively discourages academic physicians from participating in industry-sponsored, FDA-regulated speaker programs. Mr. Kindler and Mr. Taurel further state that "We believe the reasoning for many of the recommendations is directionally correct, but more often than not the potential issues addressed reflect perceptions rather than proven consequences." The full statements from these Task Force members are presented in Appendix B.

Chapter 1. Professionalism and Medical Education

Professionalism lies at the heart of medicine, and inculcating the values associated with it in future generations of physicians is a primary responsibility of academic medicine. In order that its interactions with industry consistently reflect the principles of professionalism, academic medical centers should take pains to impart the qualities of professionalism both through teaching and through the professional behaviors of faculty and staff. Professional standards should also be reflected and continuously reinforced in each institution's policies and practices in the areas of education, clinical practice, and research.

Institutional Policies and Practices

- Academic medical centers should adopt and implement policies that address specific interactions between academic medical personnel and industry and are consistent with recommendations contained in Chapter 2. These policies should reinforce and uphold institutional and individual efforts to promote a learning environment that supports professionalism and eliminates activities that undermine this objective.
- Academic medical centers should make clear to their faculty, students, and staff that to the extent certain interactions with industry are prohibited within academic medical centers, they are also prohibited off-site.
- Similarly, academic medical centers should communicate to off-site training facilities their expectation that the off-site venues will adhere to the standards of the academic center regarding interactions with industry.
- Industry should not invite academic medical center personnel to participate off-site in practices prohibited on-site.

Education for Professionalism

- Educational programs should be developed to raise the awareness among students, trainees, and faculty of challenges to professionalism presented by certain interactions with industry and to provide opportunities that help them build critical evaluation skills that reinforce high individual standards, norms, and behaviors. Specifically, the Task Force recommends a follow-on Medical School Objectives Project (MSOP) that focuses on developing learning objectives regarding professionalism and industry interactions.

Chapter 2. Benefits and Pitfalls

Substantive, appropriate, and well-managed interactions between industry and academic medicine are vital to public health, but they must be conducted in a way that is principled and upholds the public trust. Clear and well-thought-out guidelines will optimize the benefits inherent in the relationship between academic medicine and industry and minimize the risks.

Gifts to Individuals

- Academic medical centers should establish and implement policies that prohibit the acceptance of any gifts from industry by physicians and other faculty, staff, students, and trainees of academic medical centers, whether on-site or off-site. Such standards should encompass gifts from equipment and service providers as well as pharmaceutical and device providers.

Pharmaceutical Samples

- The distribution of medications in academic medical centers, including samples (if permitted), should be centrally managed in a manner that ensures timely patient access to optimal therapeutics throughout the health care system.
- If central management is not thought to be feasible, or would interfere with patient access to optimal therapeutics, the academic medical center should carefully consider whether or not there are alternative ways to manage pharmaceutical sample distribution that do not carry the risks to professionalism with which current practices are associated.

Site Access by Pharmaceutical Representatives

- To protect patients, patient care areas, and work schedules, access by pharmaceutical representatives to individual physicians should be restricted to nonpatient care areas and nonpublic areas and should take place only by appointment or invitation of the physician.
- Involvement of students and trainees in such individual meetings should occur only for educational purposes and only under the supervision of a faculty member.
- Academic medical centers should develop mechanisms whereby industry representatives who wish to provide educational information on their products may do so by invitation in faculty-supervised structured group settings that provide the opportunity for interaction and critical evaluation. Highly trained industry representatives with M.D., Ph.D., or Pharm.D. degrees would be best suited for transmitting such scientific information in these settings.

Site Access by Device Manufacturer Representatives

- Access by device manufacturer representatives to patient care areas should be permitted by academic medical centers only when the representatives are appropriately credentialed by the center and should take place only by appointment or invitation of the physician.

- Representatives should not be allowed to be present during any patient care interaction unless there has been prior disclosure to and consent by the patient, and then only to provide in-service training or assistance on devices and equipment.
- Student interaction with representatives should occur only for educational purposes under faculty supervision.

Continuing Medical Education (CME)

- Academic medical centers offering CME programs should develop audit mechanisms to assure compliance with the standards of the Accreditation Council for Continuing Medical Education (ACCME), including those with respect to content validation and meals.
- Academic medical centers should establish a central CME office through which all requests for industry support and receipt of funds for CME activity are coordinated and overseen.
- To the extent that educational programs for physicians are supported by any commercial entity, including pharmaceutical, device, equipment, and service entities, the programs should be offered only by ACCME-accredited providers according to ACCME standards.

Participation in Industry-Sponsored Programs

- With the exception of settings in which academic investigators are presenting results of their industry-sponsored studies to peers and there is opportunity for critical exchange, academic medical centers should strongly discourage participation by their faculty in industry-sponsored speakers' bureaus.
- To the extent that academic medical centers choose to allow participation of their faculty and staff in industry-sponsored, FDA-regulated programs, they should develop standards that define appropriate and acceptable involvement.
    1. Academic medical centers should require full transparency and disclosure by their personnel to the centers and when participating in such programs; and
    2. Academic medical centers should require that payments to academic personnel be only at fair market value.
- Academic medical centers should prohibit their faculty, students, and trainees from:
    1. Attending non-ACCME accredited industry events billed as continuing medical education;
    2. Accepting payment for attendance at industry-sponsored meetings; and
    3. Accepting personal gifts from industry at such events.

Industry-Sponsored Scholarships and Other Educational Funds for Trainees

- Academic medical centers should establish and implement policies requiring that:

    1. All scholarships or other educational funds from industry must be given centrally to the administration of the academic medical center;
    2. No *quid pro quo* be involved in any way; and
    3. The evaluation and selection of recipients of such funds must be the sole responsibility of the academic medical center or of a nonprofit granting entity, with no involvement by the donor industry.

Food

- With the exception of food provided in connection with ACCME-accredited programming and in compliance with ACCME guidelines, institutions should establish and implement policies stating that industry-supplied food and meals are considered personal gifts and will not be permitted or accepted within academic medical centers.
- Policies should make clear that the same standard of behavior should be met off-site.

Professional Travel

- Academic medical centers should prohibit their physicians, trainees, and students from directly accepting travel funds from industry, other than for legitimate reimbursement or contractual services.

Ghostwriting

- Academic medical centers should prohibit physicians, trainees, and students from allowing their professional presentations of any kind, oral or written, to be ghostwritten by any party, industry or otherwise.

Purchasing

- Academic medical centers should establish and implement policies that require their personnel with any financial interest (as defined by the medical center's conflict of interest policy or applicable purchasing conflict of interest policy) in any particular manufacturer of pharmaceuticals, devices, or equipment, or any provider of services, to disclose such interests according to institutional policies and to recuse themselves from involvement in purchasing decisions relevant to the conflicting interests.
- To the extent an individual's expertise is necessary in evaluating any product, that individual's financial ties to any manufacturer of that or any related product must be disclosed to those charged with the responsibility for making the decision.

Chapter 3. Unmet Needs and Opportunities

Academic medical centers and industry have the obligation to create a healthy platform for cooperation and collaboration that protects academic integrity in education, research, and patient care; can withstand public scrutiny; and builds toward the future.

The Educational Experience

- Medical schools and teaching hospitals should design curriculum standards and teaching materials for all phases of medical education—from medical school to residency to continuing medical education—that provide tools to educate students, residents, and faculty about the processes and disciplines of drug discovery, development, clinical testing, safety, therapeutics, and regulation.

Content Validation of Continuing Medical Education

- The AAMC should collaborate with ACCME to create a process by which CME offerings would be externally spot-reviewed or audited for consistency with applicable guidelines and for the presence of inappropriate influence.
- The AAMC should participate with key national medical organizations, such as the American Medical Association (AMA), the ACCME, the Society for Academic Continuing Medical Education (SACME), and other professional societies in an initiative to define the processes and structure that would best ensure the provision of sound, timely, scientifically objective CME that meets the educational needs of physicians.

Development of Information Portals

- The AAMC should convene representatives of academic medicine and industry in a cooperative effort to develop optimal information systems, including Web-based technologies, for disseminating information on new products.
- The AAMC should convene an expert panel composed of academic and industry representatives to explore new opportunities and identify best practices in information exchange between academic medicine and industry that are transparent, rely on rigorous evaluation of evidence, and are consistent with standards of professionalism.

D. Summary of Revisions of the PhRMA Guidelines , July 2008

The following has been prepared as a "White Paper" by Mc Dermott Will and Emery as a document entitled "PhRMA revises code on interactions with Healthcare Professional. Reducing industry spending while increasing transparency obligations." July 15, 2008. Address of article is http://www.mwe.com/info/news/wp0708b.htm.

Narrowing the Scope of Permissible Financial Relationships with Healthcare Professionals

When compared to the 2002 Code, the terms of the 2008 Code further limit the scope of permissible industry relationships with healthcare professionals as follows:

2002 CODE	2008 CODE
The 2002 Code permitted gifts to physicians primarily for the benefit of patients and nominal practice-related reminder items (*e.g.* pens, pads, mugs) in the amount of $100 or less. 2002 Code, § 7(a).	The 2008 Code adds the following restrictions and limitations on the types of gifts that may be provided to physicians: (a) it forbids non-educational gifts (*e.g.* pens, pads, mugs) even if they are of minimal value; and (b) it allows only gifts that are designed primarily for the education of patients or healthcare professionals (*i.e.,* to communicate important information about the nature and characteristics of prescription medicines and the diagnosis and treatment of disease), but only if they are $100 or less in value and they have no value to healthcare professionals outside their professional duties. 2008 Code, § 10, 11.
The 2002 Code permitted industry representatives to provide occasional and modest meals to healthcare professionals outside of a practice setting (*i.e.* office, hospital) even when not in connection with a speaker program. 2002 Code, §2.	The 2008 Code now forbids any meals outside of the office or hospital setting other than in connection with speaker programs, and maintains the requirement that all meals within the practice setting be occasional and modest. 2008 Code, § 2.
The 2002 Code stated that the selection of consultants and speakers should be based on criteria directly related to the purpose of the event. 2002 Code, § 4(a).	The 2008 Code now requires industry to define specific criteria for the selection or retention of speakers and consultants. 2008 Code, § 6.
The 2002 Code permitted social or entertainment events at continuing medical education (CME) or other third-party scientific and educational conferences or professional meetings if clearly subordinate in terms of time and emphasis. 2002 Code, § 3(c).	The 2008 Code now prohibits entertainment at industry-sponsored meetings with healthcare professionals, including consultants, as well as any healthcare professional who is not a salaried employee. 2008 Code, §§ 3, 6.
The 2002 Code stated that the location of meetings for consultants and speakers should be conducive to the services provided. 2002 Code, § 3(c).	The 2008 Code now specifically forbids resorts as locations for any such meetings. 2008 Code, § 7.
The 2002 Code stated that industry sponsorship of CME through independent companies must allow the CME provider to have responsibility for control over selection of content, faculty, educational methods, materials and venue. 2002 Code, § 3(a).	The 2008 Code states that industry may no longer provide *any* advice or guidance regarding educational program content or faculty, even if asked by the CME provider, and further, should follow standards established by a CME accrediting body (*i.e.,* the Accreditation Council for Continuing Medical Education) regarding commercial support. 2008 Code, § 4.
The 2002 Code permitted industry to provide financial support for meals or receptions at CME events if compliant with the CME provider's policies. 2002 Code, § 3(c).	The 2008 Code now forbids the provision of meals or receptions at CME events, although it permits CME providers to apply general unrestricted financial support from industry to a CME event to meals for all participants. The 2008 Code states that financial support for CME should not be an inducement or reward for prescribing a particular course of treatment. 2008 Code, § 4.

New Provisions Mandating Increased Disclosure, Transparency and Accountability

The 2008 Code also includes the following new mandates for industry disclosure, transparency and accountability:

1. Each industry company must individually and independently determine a cap on annual spending for speaker and consultant fees. 2008 Code, § 7.

2. Industry should require all healthcare professional speakers and consultants that help determine formularies or develop practice guidelines to disclose to the formulary or practice development committee the existence and nature of their relationships with the company, for a period of two years following termination of the speaking or consulting arrangement. 2008 Code, § 8, Question 25.

3. Industry and CME faculty should clearly distinguish between promotional speaker programs and independent CME, and industry should periodically monitor speaker programs for compliance with regulatory requirements. 2008 Code, § 7.

4. Industry financial support for CME should be intended to support education on a full range of treatment options, not the promotion of a particular medicine. 2008 Code, § 4.

5. Each industry company should develop and enforce policies for use of non-patient identified prescriber data and permit physicians to opt out of disclosing such data to company sales agents. 2008 Code, § 12.

6. Promotional materials should be accurate and not misleading, make only supported claims, reflect the balance between risks and benefits, and should be consistent with regulatory requirements. 2008 Code, § 1.

7. Each industry company should ensure that all its sales representatives are trained, assessed periodically regarding compliance, and be subject to appropriate disciplinary action if non-compliant. 2008 Code, § 14.

8. The 2008 Code calls on industry to publicly commit to abide by the 2008 Code. It specifically recommends formal, self-certification of compliance by both the chief executive officer and chief compliance officer and authorizes PhRMA to post names and contact information for company compliance officers. Moreover, PhRMA has stated that it will post on its website the names of companies that publicly make a commitment to adhere to the 2008 Code, the status of annual certifications, and indicate when a company has obtained external verification of compliance with the 2008 Code. 2008 Code, § 15.

E. ACCME Standards for commercial support to ensure the independence of Continuing Medical Education (CME)Activities

http://www.ama-assn.org/ama1/pub/upload/mm/455/accmecommercial.pdf

The ACCME Standards for Commercial Support℠

Standards to Ensure Independence in CME Activities

STANDARD 1: Independence

1.1 A CME provider must ensure that the following decisions were made free of the control of a commercial interest. (See www.accme.org for a definition of a 'commercial interest' and some exemptions.)

(a) Identification of CME needs;
(b) Determination of educational objectives;
(c) Selection and presentation of content;
(d) Selection of all persons and organizations that will be in a position to control the content of the CME;
(e) Selection of educational methods;
(f) Evaluation of the activity.

1.2 A commercial interest cannot take the role of non-accredited partner in a joint sponsorship relationship.⌘

STANDARD 2: Resolution of Personal Conflicts of Interest

2.1 The provider must be able to show that everyone who is in a position to control the content of an education activity has disclosed all relevant financial relationships with any commercial interest to the provider. The ACCME defines "'relevant' financial relationships" as financial relationships in any amount occurring within the past 12 months that create a conflict of interest.

2.2 An individual who refuses to disclose relevant financial relationships will be disqualified from being a planning committee member, a teacher, or an author of CME, and cannot have control of, or responsibility for, the development, management, presentation or evaluation of the CME activity.

2.3 The provider must have implemented a mechanism to identify and resolve all conflicts of interest prior to the education activity being delivered to learners.⌘

STANDARD 3: Appropriate Use of Commercial Support

3.1 The provider must make all decisions regarding the disposition and disbursement of commercial support.

3.2 A provider cannot be required by a commercial interest to accept advice or services concerning teachers, authors, or participants or other education matters, including content, from a commercial interest as conditions of contributing funds or services.

3.3 All commercial support associated with a CME activity must be given with the full knowledge and approval of the provider.

Written agreement documenting terms of support

3.4 The terms, conditions, and purposes of the commercial support must be documented in a written agreement between the commercial supporter that includes the provider and its educational partner(s). The agreement must include the provider, even if the support is given directly to the provider's educational partner or a joint sponsor.

3.5 The written agreement must specify the commercial interest that is the source of commercial support.

3.6 Both the commercial supporter and the provider must sign the written agreement between the commercial supporter and the provider.

Expenditures for an individual providing CME

3.7 The provider must have written policies and procedures governing honoraria and reimbursement of out-of-pocket expenses for planners, teachers and authors.

3.8 The provider, the joint sponsor, or designated educational partner must pay directly any teacher or author honoraria or reimbursement of out-of-pocket expenses in compliance with the provider's written policies and procedures.

3.9 No other payment shall be given to the director of the activity, planning committee members, teachers or authors, joint sponsor, or any others involved with the supported activity.

3.10 If teachers or authors are listed on the agenda as facilitating or conducting a presentation or session, but participate in the remainder of an educational event as a learner, their expenses can be reimbursed and honoraria can be paid for their teacher or author role only.

Expenditures for learners

3.11 Social events or meals at CME activities cannot compete with or take precedence over the educational events.

3.12 The provider may not use commercial support to pay for travel, lodging, honoraria, or personal expenses for non-teacher or non-author participants of a CME activity. The provider may use commercial support to pay for travel, lodging, honoraria, or personal expenses for bona fide employees and volunteers of the provider, joint sponsor or educational partner.

Accountability

3.13 The provider must be able to produce accurate documentation detailing the receipt and expenditure of the commercial support. ⌘

STANDARD 4. Appropriate Management of Associated Commercial Promotion

4.1 Arrangements for commercial exhibits or advertisements cannot influence planning or interfere with the presentation, nor can they be a condition of the provision of commercial support for CME activities.

4.2 Product-promotion material or product-specific advertisement of any type is prohibited in or during CME activities. The juxtaposition of editorial and advertising material on the same products or subjects must be avoided. Live (staffed exhibits, presentations) or enduring (printed or electronic advertisements) promotional activities must be kept separate from CME.

- For *print*, advertisements and promotional materials will not be interleafed within the pages of the CME content. Advertisements and promotional materials may face the first or last pages of printed CME content as long as these materials are not related to the CME content they face *and* are not paid for by the commercial supporters of the CME activity.
- For *computer based*, advertisements and promotional materials will not be visible on the screen at the same time as the CME content and not interleafed between computer 'windows' or screens of the CME content
- For *audio and video recording*, advertisements and promotional materials will not be included within the CME. There will be no 'commercial breaks.'
- For *live, face-to-face CME*, advertisements and promotional materials cannot be displayed or distributed in the educational space immediately before, during, or after a CME activity. Providers cannot allow representatives of Commercial Interests to engage in sales or promotional activities while in the space or place of the CME activity.

4.3 Educational materials that are part of a CME activity, such as slides, abstracts and handouts, cannot contain any advertising, trade name or a product-group message.

4.4 Print or electronic information distributed about the non-CME elements of a CME activity that are not directly related to the transfer of education to the learner, such as schedules and content descriptions, may include product-promotion material or product-specific advertisement.

4.5 A provider cannot use a commercial interest as the agent providing a CME activity to learners, e.g., distribution of self-study CME activities or arranging for electronic access to CME activities. ⌘

STANDARD 5. Content and Format without Commercial Bias

5.1 The content or format of a CME activity or its related materials must promote improvements or quality in healthcare and not a specific proprietary business interest of a commercial interest.

5.2 Presentations must give a balanced view of therapeutic options. Use of generic names will contribute to this impartiality. If the CME educational material or content includes trade names, where available trade names from several companies should be used, not just trade names from a single company.⌘

STANDARD 6.Disclosures Relevant to Potential Commercial Bias

Relevant financial relationships of those with control over CME content

6.1 An individual must disclose to learners any relevant financial relationship(s), to include the following information:

- The name of the individual;
- The name of the commercial interest(s);
- The nature of the relationship the person has with each commercial interest.

6.2 For an individual with no relevant financial relationship(s) the learners must be informed that no relevant financial relationship(s) exist.

Commercial support for the CME activity.

6.3 The source of all support from commercial interests must be disclosed to learners. When commercial support is 'in-kind' the nature of the support must be disclosed to learners.

6.4 'Disclosure' must never include the use of a trade name or a product-group message.

Timing of disclosure

6.5 A provider must disclose the above information to learners prior to the beginning of the educational activity. ⌘