

N.B.: This policy was approved by the Advisory Board of the Medical Faculty on March 25, 2009. It will take effect on July 1, 2009. Section 2(d) will take effect on July 1, 2010.

Johns Hopkins Medicine Policy on Interaction with Industry

Introduction

In order to fully realize the benefits of biomedical research and education and ensure continued advances in the prevention, diagnosis, and treatment of disease, Johns Hopkins Medicine must engage in an effective and principled partnership with industry. Relationships such as those involving research collaborations, technology transfer, and educational programs can yield benefits for the JHM missions of research, education, and clinical care.

In recent years, public trust in the partnership between academia and industry has been eroded by academic medical centers' and health care providers' reliance on industry support and in particular on gifts and other forms of support that create possible conflicts of interest. The marketing missions of pharmaceutical and medical device manufacturers have become intertwined with medical education and practice, with a frequent focus on leaders in academic medicine. Industry influence may be subtle, and health care providers often are not aware of the extent to which their judgment may be influenced when they depend on industry to support educational activities or provide drug samples.^{1 2}

To retain the trust of patients and the public, the Johns Hopkins University School of Medicine and The Johns Hopkins Health System Corporation adopt this policy on interaction with industry. The goal of the policy, which consists of both rules and guidance, is to foster a culture in which Johns Hopkins faculty, staff, employees, students, and trainees exercise independent judgment in all their activities and practice evidence-based, cost-effective medical care. Insofar as they support these goals, appropriate interactions with industry are desirable, since they will help move ideas into development, production, and practice for the welfare of patients and the betterment of public health.

1) Application of the Policy

In general, this policy applies to full-time and part-time faculty and staff (the term "staff" includes all employees), students, trainees, and volunteers of all Johns Hopkins Medicine member organizations³

¹ Social scientists have documented the unconscious influence of gifts and payments on decision-making. See, for example, Montague, P.R., King-Casas, B., & Cohen, J.D. (2006) Imaging valuation models in human choice. *Annual Review of Neuroscience*, 29, 417–448; Chugh, D., Bazerman, M.H., & Banaji, M.R. (2005). Bounded Ethicality as a Psychological Barrier to Recognizing Conflicts of Interest. In Moore, D. A., Cain, D.M., Loewenstein, G. and Bazerman, M. (eds.), *Conflicts of Interest: Problems and Solutions from Law, Medicine and Organizational Settings*. London: Cambridge University Press, 74–95; and King-Casas, B., Tomlin, D., Anen, C., Camerer, C.F., Quartz, S.R., & Montague, P.R. (2005). Getting to know you: Reputation and trust in a two-person economic exchange. *Science*, 308, 78–83.

² *Industry Funding of Medical Education*, Report of an AAMC Task Force, June 2008

³ Johns Hopkins University School of Medicine; The Johns Hopkins Health System Corporation (includes various healthcare delivery sites); The Johns Hopkins Hospital; Johns Hopkins Bayview Medical Center Inc.; Johns Hopkins Community Physicians Inc.; Johns

and all Johns Hopkins Medicine member sites. Some provisions of the policy vary with respect to applicability, and details are set forth below.

Full-time and part-time faculty, staff, and volunteers: Unless specific exceptions are noted, this policy applies to all full-time and part-time faculty and staff, and to volunteers with respect to activity at any JHM member organization site and all activity conducted under the auspices of or using the name of any JHM member organization.

Students and trainees: Unless specific exceptions are noted, this policy applies to all students and trainees with respect to activity at any JHM member organization site and activity conducted under the auspices of or using the name of any JHM member organization insofar as they may be perceived as representing Johns Hopkins.⁴

This policy does not limit or substitute for related institutional policies such as those on conflict of commitment and interest, continuing medical education (CME), site access, philanthropy, purchasing, the JHU Statement of Ethical Standards, etc. However, to the extent this policy is more stringent than related institutional policies, this policy will govern.

2) Policy

a) **Gifts⁵ to Individuals from Industry⁶**

Gifts, even small gifts, carry an implied expectation of reciprocity. Accepting a coffee mug or mouse pad from a pharmaceutical sales representative may not consciously affect one's decision-making, but the interaction with the giver or the presence of the item in an office is likely to make one think positively of the donor or product and cloud one's clinical judgment.

To avoid the risk of conscious or subconscious bias in decision-making, it is the Johns Hopkins Medicine policy that faculty and staff, employees, students, trainees, and volunteers may not accept gifts or entertainment (see below for food and meals), regardless of value, from pharmaceutical

Hopkins Employer Health Programs Inc. (EHP); Howard County General Hospital; Johns Hopkins HealthCare LLC; Johns Hopkins Home Care Group Inc. and subsidiaries; and Johns Hopkins Medicine International LLC.

JHM member organizations other than the Johns Hopkins University School of Medicine, the Johns Hopkins Hospital and the Johns Hopkins Bayview Medical Center may adopt their own policies on interaction with industry, provided they comply with and are no less stringent than this policy. There should be no differences in policies governing interaction with industry among the Johns Hopkins University School of Medicine, the Johns Hopkins Hospital and the Johns Hopkins Bayview Medical Center.

⁴ One example of an appropriate exception follows. In the setting of a job interview with a prospective employer, for convenience a trainee may accept a meal on-site from a pharmaceutical or medical device company.

⁵ For purposes of this policy, a gift is defined as any item, product, or service of any value. The term includes, but is not limited to, pens, notepads, mouse pads, memory sticks, article reprints, coffee mugs, meals and entertainment, travel, food, cash, equity or other ownership interest.

⁶ In this policy, the term "industry" means biomedical, pharmaceutical and medical device companies and companies that make other products used in the treatment of patients or the provision of medical care. Other JHM policies (e.g., purchasing policies, ethical standards) govern interactions with companies in other fields (e.g., IT vendors).

companies or medical device manufacturers or suppliers with respect to any activity at any JHM member organization site and any activity conducted under the auspices of or using the name of any JHM member organization. Adherence to this policy in other settings is strongly encouraged.

Certain limited exceptions are appropriate. It is permissible to accept medical or scientific books if neither the book nor its packaging carries the name or logo of a biomedical, pharmaceutical, or medical device company and if the books are distributed through a School department or via JHM. Anatomical models and illustrations (e.g., posters) may be accepted provided they do not carry the name or logo of a biomedical, pharmaceutical, or medical device company and if they are distributed through a School department or via JHM. Departments may publicly acknowledge the support of specific companies as long as the acknowledgement is not tied to a particular activity or program.

Consulting arrangements involving personal compensation without commensurate associated duties are considered gifts and are prohibited. Specific policies regarding outside consulting are set forth in the School of Medicine's policy on conflict of commitment and in JHM organizations' personnel policies.

Industry promotional items may not be displayed in any JHM facility, with the exception of formal exhibit areas during an accredited CME activity.

See section 2(c) below for the policy on gifts to support education, patient care, and research.

b) Food

With certain exceptions, outlined below, industry-supplied food and meals are considered personal gifts and will not be permitted and may not be accepted at any JHM member organization site, in connection with activity conducted under the auspices of or using the name of any JHM member organization or in the context of professional activity off-site.

Industry-supplied or supported food may be accepted in connection with programs accredited by the Accreditation Council on Continuing Medical Education (ACCME) and in compliance with ACCME guidelines; in the course of providing legitimate, approved consulting or advisory services; in the context of professional society meeting events open to all meeting attendees; and, in the context of meetings directly related to ongoing sponsored research projects. Professional society meetings often involve large group events with food provided by industry. JHM faculty, staff, students, and trainees may participate in these events, but are strongly encouraged to urge their professional societies to end the practice of relying on industry to support such events. When invited to a small group meal by an industry representative, JHM faculty and staff must pay for their own food and drink.

Unrestricted financial gifts to the institution (as specified in Section 2(c)) may be used in part to provide food for JHM personnel; however, the decision to use gift funds to provide food will be made at the sole discretion of the department or division director. As with any unrestricted gift, departments may publicly acknowledge the unrestricted support of specific companies as long as the acknowledgement is not tied to a particular activity or program. When a company supports a particular lecture or educational event in accordance with this policy, the support must be disclosed and acknowledged as described elsewhere in this policy.

Related policies: SOM, JHH, JHBMC, HCGH, other clinical facilities

c) Unrestricted Gifts

Through unrestricted gifts, industry generously supports the educational, research, and patient care missions of Johns Hopkins. Gifts must be made to the University or JHHS and deposited in a departmental account.⁷ There may be no *quid pro quo*, nor any limitations nor conditions placed on gifts that are inconsistent with Fund for Johns Hopkins Medicine policies and applicable regulations. In-kind gifts (e.g., equipment, software) to the institution may be accepted if they are provided in accordance with applicable policies on research administration, development, and hospital requirements and are reviewed by institutional counsel⁸.

Gifts from industry may be used by the department to support faculty and staff education, research, and/or patient education. Distribution of the funds will be at the discretion of the department director, who will disseminate the criteria for requesting funds to all faculty members in the department. Annually, each department will submit to the Dean's Office a list of gifts received from industry in the previous 12 months and specific information as to how the funds were used. Departments may publicly acknowledge the unrestricted educational support of specific companies as long as the acknowledgement is not tied to a particular activity or program. When a company supports a particular lecture or educational event in accordance with this policy, the support must be disclosed and acknowledged in connection with the event.

Faculty members may accept prizes and awards for scientific or medical achievements from company-supported foundations and organizations if the recipient is chosen through an established, independent process of scientific review. If awarded to support the individual's research, cash awards may be deposited in the recipient's discretionary account. For purposes of this policy, prizes and awards are not considered gifts.

See also <http://www.hopkinsmedicine.org/support/index.html>.

d) Pharmaceutical Samples

The practice of accepting free pharmaceutical samples risks interference with one's prescribing practices since industry representatives often provide the newest and most costly drugs. Therefore, free pharmaceutical samples and vouchers for free pharmaceutical samples may not be accepted.

The foregoing will take effect one year from the effective date of this policy so that affected providers and clinics can make the needed changes.

When samples are necessary for patient education (e.g., instructing patients in the use of inhalers), they may be accepted, provided they do not carry the name of a company or the name of the company is covered.

⁷ In large departments, this role may be assumed by divisions.

⁸ Donations of equipment by vendors can lead to legal exposure under anti-kickback statutes if use is billed to third-party payors.

Johns Hopkins faculty physicians and other hospital staff will educate staff and trainees about and inform patients of affordable options for obtaining medicines. Examples are pharmaceutical assistance programs, vouchers, and large retail chains with low-cost medicines.

See also: JHH, JHBMC, and other JHHS clinical facilities' Pharmacy policies and <http://ssc.jhmi.edu/supplychain/guides/JHHSVendorPolicyManual.pdf>.

e) Site Access by Pharmaceutical, Medical Testing, and Other Industry Representatives (*see Section 2(f) for Site Access by Medical Device Industry Representatives*)

To protect patients, patient care areas (including physician offices where patients may be seen), and work schedules, access by pharmaceutical, medical testing and other industry representatives to individual physicians must be restricted to non-patient care areas. Access will be permitted only on invitation from a physician, nurse, pharmacist, respiratory therapist, or other professional healthcare staff member. Access also will be permitted on invitation by a hospital materials management representative where the purpose of the visit is to train staff on, repair, or evaluate equipment already procured by the hospital. Invitations should be appropriately reflected in administrative records such as calendars.

Industry representatives who are qualified healthcare professionals or scientists and who wish to provide information on their products may do so if invited by a faculty physician and only in faculty-supervised, structured group settings that provide the opportunity for interaction and critical evaluation. Involvement of students and trainees in such meetings should occur only with direct and continuous supervision by the faculty member who issued the invitation. No individual whose primary purpose for being at JHM is marketing may participate in such meetings. Industry promotional material may not be exhibited or displayed at any JHM site, except at JHM CME events and in accordance with ACCME standards.

Industry representatives may attend grand rounds on occasion for educational purposes if a) expressly invited by a department or division director or faculty member, and b) no patient-specific information is presented or discussed at the meeting.

Related policies: JHH, JHBMC, HCGH, other clinical facilities

f) Site Access by Medical Device Industry Representatives

To protect patients, patient care areas (including physician offices where patients may be seen), and work schedules, access by medical device representatives to individual physicians must be restricted to non-patient care areas. Access will be permitted only on invitation from a physician, nurse, pharmacist, respiratory therapist, or other professional healthcare staff member. Access also will be permitted upon invitation by a hospital materials management representative where the purpose of the visit is to train staff on, repair, or evaluate equipment already procured by the hospital. Invitations should be appropriately reflected in administrative records such as calendars.

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Industry representatives may attend grand rounds on occasion for educational purposes if a) expressly invited by a department or division director or faculty member, and b) no patient-specific information is presented or discussed at the meeting.

Device or other industry representatives are permitted to be present during patient care interactions only if all of the following conditions are met: i) the purpose of the representative's visit is to provide in-service training or assistance to JHM staff on devices or equipment; ii) there is a formal written agreement between the appropriate JHM member entity and the representative's employer specifying the terms and conditions of the representative's presence, which may not be less restrictive than the conditions outlined in this policy; iii) the representative is appropriately credentialed in accordance with the JHM facility's credentialing policies; and iv) there has been prior written disclosure to the patient (or his or her family that industry representatives may be present in the procedure area. Device or other industry representatives may be present under these conditions and remain in the procedure room or operating room with trainees present in accordance with CMS regulations and Johns Hopkins policies regarding resident/trainee supervision.

Related policies: JHH, JHBMC, HCGH, other clinical facilities' vendor access policies and vendor relations policies

g) Continuing Medical Education at JHM Sites or Using the JHM Name or Resources

The JHU SOM Office of Continuing Medical Education (OCME) is the sole provider of programs offering continuing medical education credit under the Johns Hopkins name. All requests for industry support and receipt of funds for continuing medical education activity must be managed centrally by the OCME. The OCME will audit its courses to ensure compliance with ACCME standards, including those with respect to content validation and meals.

All industry-sponsored continuing medical education programs at JHM sites or using the JHM name or resources must comply with ACCME standards (whether or not CME credit is offered). For continuing education programs at JHM sites or using the JHM name or resources and sponsored by industry but not offering AMA PRA Category 1 CME creditTM, prior approval of the general terms of the program by the Vice Dean for Education will be required to ensure the activity is of legitimate educational value and is consistent with Johns Hopkins Medicine standards. For approved activities, the company's support must be disclosed in connection with the event.

JHM faculty, staff, students, and trainees should not accept more than modest meals or social activities in connection with non-ACCME-accredited continuing medical education programs and funding cannot be accepted to support social activities that do not have an educational component. Industry funding may not be accepted to support the costs of internal department meetings, retreats, or social events.

See also <http://www.hopkinscme.edu/About/about.aspx>.

h) Participation in Industry-Sponsored Programs

Speaking for Industry. Faculty members may speak at an industry-sponsored program only if the faculty member retains full control and authority over professional material the faculty member presents and does not allow such communications or presentations to be subject to prior approval by any commercial interest other than approval for the use of proprietary information. Activities with any of the following characteristics may not be undertaken at any location, whether on-site or off-site: a company has the contractual right to dictate what the faculty member says; a company (not the faculty member) creates the slide set (or other presentation materials) and has the final approval of all content and edits;⁹ the faculty member receives compensation from the company and acts as the company's employee or spokesperson for the purposes of dissemination of company-generated presentation materials or promotion of company products; and/or a company controls the publicity related to the event. Some of the prohibited activities occur in the context of "speakers' bureaus," but the conditions of the speaking engagement must govern the decision as to whether or not the activity is acceptable under this policy.

Exceptions to this policy may be granted by the School of Medicine Office of Policy Coordination to allow faculty participation in training of providers for a new device or procedure under applicable regulations (e.g., FDA-mandated training).

At any presentation for which the faculty member has received industry payment or support, the faculty member must fully disclose the name of the company and the nature of the support.

Attendance at industry-sponsored promotional events off site. Faculty members, trainees, students, and staff are strongly discouraged from attending promotional speaking events sponsored by industry at non-JHM sites. If they attend, they should pay for their own meals.

Consulting for industry. Faculty may consult with industry to provide scientific advice, provided payment is at fair market value; the arrangement is governed by a written agreement specifying the service(s) to be provided; the arrangement complies with the School of Medicine's policy on conflict of commitment; the arrangement is reported to the Office of Policy Coordination; and the faculty member discloses his/her relationship as required under this policy and the policies on conflict of interest and commitment.

Industry-sponsored programs at JHM sites. Funds from industry may be used to support individual lectures by faculty from other institutions, provided the sponsoring JHM department has complete control over the choice of speaker, the setting, invitations to attendees, and other arrangements. Scientific or medical professionals representing the sponsoring company may attend the program, but they may not engage in marketing activity and no company or product literature or exhibits may be distributed or displayed. However, the company's support should be publicly disclosed and acknowledged. Industry support of medical educational programs involving more than an individual

⁹ Slides prepared by a company that depict generic anatomical or biological structures or functions may be used in a presentation by a faculty member if 1) the content is accurate and of high quality, and 2) no company logo or name appears on the slide.

lecture is addressed in Section 2(g).

Industry support may be accepted for scientific conferences and symposia at JHM sites or at other sites using the JHM name or resources under the following conditions: i) the program is scientific and not clinical, i.e., its primary purpose is to discuss basic science and not the diagnosis or treatment of disease or other aspects of medical practice; ii) the content of the program, choice of speakers, invitations to attendees, and all other arrangements are controlled by a JHM department or division, iii) no company marketing material is provided or distributed, iv) sponsorship is acknowledged and disclosed in the program material, and b) speakers disclose any relationships they have with the sponsor(s).

Disclosure. Faculty must disclose all relevant payments from and interests in industry in related presentations and publications and in lectures to students and trainees.¹⁰

See also

http://www.hopkinsmedicine.org/som/faculty/policies/facultypolicies/conflict_commitment.html and, http://www.hopkinsmedicine.org/som/faculty/policies/facultypolicies/speakers_bureau_policy.html.

i) Industry-Sponsored Scholarships and Other Educational Funds for Trainees

Scholarships and other educational funds from industry or not-for-profit organizations substantially supported by industry must be given to a department or division. There may be no expressed or implied *quid pro quo* for the funds. The evaluation and selection of recipients of such funds is the sole responsibility of the School of Medicine or one of its academic departments, with no involvement by the donor organization or company. When such conditions are met, the donor may be acknowledged in appropriate settings.

Related policies: SOM, JHH, and JHBMC student and JHM entity student and house staff policies

j) Professional Travel

Faculty, staff, students, and trainees may accept travel funds from industry in the following circumstances: i) for legitimate reimbursement for travel to provide contractual services, such as approved consulting activity, ii) to view capital equipment in situ if the equipment is being considered for purchase by a JHM entity; or iii) to participate in meetings directly related to ongoing sponsored research. Unrestricted gifts to the institution (as specified in Section 2(c)) may be used in part to support travel for JHM personnel attending professional meetings; however, the decision to use gift funds for travel expenses will be made at the sole discretion of the department director. Students and trainees may accept travel funds from scientific societies, whether or not industry is the source of funds, provided the society controls the selection of the recipient of travel support.

k) Ghost-writing and Ghost-authoring

¹⁰ If, for example, a faculty member consults for a company that manufactures hypertension drugs, when lecturing about the treatment of hypertension, the faculty member should disclose to students that he or she is a) a consultant to a company with products in the field, b) the name of the company, and c) the form of remuneration (cash, stock, etc.).

Faculty, staff, students, and trainees are responsible for publications listing them as authors. They may not permit their professional publications or presentations of any kind, oral or written, regardless of medium, to be ghost-written by any party. Authorship on the part of faculty, staff, students, and trainees should be offered and accepted in accordance with the standards set forth in the School of Medicine's Policy on Responsible Conduct of Research. Faculty, staff, students, and trainees may not participate in ghost-writing or ghost-authoring of professional presentations of any kind, oral or written, regardless of medium.

See also

http://www.hopkinsmedicine.org/som/faculty/policies/facultypolicies/responsible_conduct.html#IV.

l) Purchasing

If a faculty or staff member or a student or trainee (or their spouse, domestic partner or dependent children) has a financial or ownership interest (for example, stock, stock options, employment in the case of a spouse) or a fiduciary role in, or receives payments from a pharmaceutical or medical device manufacturer or distributor and the individual has authority or influence over a JHM organization's purchases from the company, he or she must report the interest to the head of the relevant administrative or academic unit and to the appropriate purchasing official. The individual must recuse himself or herself from involvement in purchasing decisions relevant to the conflicting interests as follows: for one year after the receipt of the last payment (to the individual or a member of his/her immediate family) from the company, in the case of consulting/advisory or royalty payments; for as long as the individual (or a member of his/her immediate family) has an equity interest in the company; for one year after a member of the individual's immediate family terminates employment with the company); and for one year after the end of the fiduciary relationship on the part of the individual or a member of his/her immediate family.

To the extent an individual's expertise is necessary in evaluating any product, the individual must report his or her financial or fiduciary ties (or those of members of his/her immediate family) to any manufacturer of the product to those responsible for making the procurement decision. The individual may provide information, but must recuse him or herself from voting on purchasing decisions relevant to the conflicting interest.

There may be no express or implied quid pro quo, such as a promise of purchases, in connection with the provision of educational support, research support, or any other payment or gift of any kind from industry to JHM or any of its faculty, staff, or students.

Faculty, staff, students, and trainees also should be familiar with the purchasing and procurement policies of the relevant JHM member organizations.

See also http://www.jhu.edu/news_info/policy/ethical2.html, and JHH, JHBMC, and JHHS Vendor Policy Guides.

m) Clinical Care

JHM physicians are expected to make treatment decisions, prescribe drugs, and select medical devices on the basis of sound scientific and medical evidence. If a JHM physician (or their spouse, domestic partner or dependent children) has a financial or ownership interest (e.g., stock, stock options, or employment) or a fiduciary role in, or receives payments (e.g., royalty or consulting) from industry and in the course of his or her clinical practice prescribes medicines or selects medical devices manufactured or sold by industry, the physician should be especially careful to ensure that his or her medical decisions are made on the basis of sound scientific evidence.

n) Research

The School of Medicine's policy on conflict of interest sets forth the rules governing investigators' financial interests as they relate to the design, conduct, and reporting of research. The policy on conflict of interest is available at http://www.hopkinsmedicine.org/som/faculty/policies/facultypolicies/conflict_interest.html. Policies governing sponsorship of research are available at <http://www.hopkinsmedicine.org/Research/ora/index.html>.

3) Education, Guidance, Monitoring

Each JHM entity must publicize this policy to its faculty, staff, employees, trainees, and students. Questions should be referred to the appropriate administrative or academic unit director, who may in turn consult with the individual or office designated by the JHM entity as having responsibility in this area and/or the JHHS or JHU General Counsel's Office, as appropriate.

Local policies of JHM member entities or their sub-units must comply with and be no less stringent than this policy. Each JHM unit will develop procedures for training and monitoring compliance with the policy.

4) Sanctions for Failure to Comply

In the case of a single instance of an inadvertent failure to comply with this policy, the chief or director of the appropriate administrative or academic unit or division will remind the involved individual(s) of their obligation to comply with the policy. In the case of repeated or deliberate failure to comply with this policy, the matter will be reviewed by the chief or director of the appropriate administrative or academic unit or division in accordance with applicable JHM entity policies on staff conduct, professional misconduct, or the like. If the involved individual is the administrative head of a JHM member entity, the matter will be referred to the person to whom that individual reports.

5) Questions

Questions about this policy should be directed to the Office of Policy Coordination. See <http://www.hopkinsmedicine.org/Research/OPC/index.html>.