

## **New Conflict of Interest Policy Regarding Education and Clinical Care for P&S Faculty**

### **Introduction**

As University Officers of instruction, research and/or administration, the faculty of the Columbia College of Physicians and Surgeons (P&S Faculty) have responsibilities for research, education, clinical service, administration and other professional duties. For students and trainees, P&S Faculty not only provide training but also serve as models of professional conduct. In carrying out all of their responsibilities, P&S Faculty are expected to uphold high standards of professional integrity.

One aspect of professional integrity that is addressed in a variety of University and CUMC-wide policies is conflicts of interest. P&S Faculty are bound by these policies, which focus primarily on conflicts of interest with respect to research, intellectual property and administrative functions such as purchasing.

The purpose of this new P&S COI Policy is to re-inforce some general principles set forth in University policies and to address in detail two areas particularly relevant to P&S: clinical care and medical education. These critical P&S activities must not be compromised by conflict of interest or even the appearance of conflict. This stance is consistent with current standards set by the Association of American Medical Colleges ([aamc.org](http://aamc.org), ref 1,2), the Accreditation Council for Graduate Medical Education ([acgme.org](http://acgme.org)) and the Accreditation Council for Continuing Medical Education ([accme.org](http://accme.org)), among others.

Academic-industry collaborations are encouraged by the Bayh-Dole Act of 1980 (3). Nationally, relationships between medical school faculty and commercial entities are widespread (4,5), especially in clinical activities (6). As a consequence of academic-industry relationships, potential questions may arise regarding the intellectual independence of faculty who are involved with commercial enterprises (7). Even perceived conflicts of interest can undermine the credibility of academic and clinical functions. Interactions with industry should be conducted to avoid or minimize conflicts of interest. When real or potential conflicts arise, they must be promptly and appropriately addressed.

To avoid, identify and, if necessary, address potential conflicts of interest, this Policy requires all full- and part- time P&S Faculty, both clinical and pre-clinical, to adhere to the new policy described herein. This policy also requires that P&S faculty submit an annual Conflicts of Interest disclosure statement of significant commercial support (defined below) pertaining to education/training and clinical service, in addition to other University conflicts of interest disclosure requirements, such as those pertaining to research and administration.

This Policy adds to the existing University policies. To the extent there are other University policies or federal or state laws that govern COI issues, faculty must abide by them. P&S Faculty adherence to these guidelines for limiting potential or perceived conflicts will help avoid conflicts of interest. Annual disclosure in itself does not constitute avoidance or management of conflicts of interest.

## Implementation

The Vice Dean for Academic Affairs at CUMC will oversee implementation of this policy, in coordination with other University offices involved in conflicts of interest disclosure and management, including the offices of the Executive Vice President for Research and the General Counsel. Consistent with University policy, Department Chairs and other supervisors are charged with maintaining institutional standards within their areas of responsibility and are required to notify the Vice Dean of any significant violations of these guidelines on conflicts of interest. Any issues that are not resolved administratively will be referred to a P&S COI Committee, administered by the Vice Dean for Academic Affairs at CUMC. This committee will work jointly with the standing CUMC COI Committee on Research when COI committee inquiries involve research activities. These committees comprise senior members of the CUMC faculty, with *ex officio* representation from the offices of the Dean of the Faculty of Medicine and the University's Office of the General Counsel. All financial and other personal information related to faculty disclosures should be kept confidential and shared only on a need-to-know basis.

P&S Faculty must know and abide by the applicable conflicts of interest policies and, if needed, adhere to plans to manage or monitor conflicts as determined by the appropriate University dean, other officer, director or committee. The Senior Associate Dean for Student Affairs provides oversight for conflicts of interest issues involving P&S students.

## Citations

1. Protecting Patients, Preserving Integrity, Advancing Health: A Report of the AAMC-AAU Advisory Committee on Financial Conflicts of Interest in Human Subjects Research. AAMC February 2008. [www.aamc.org/publications](http://www.aamc.org/publications)
2. Industry Funding of Medical Education: Report of an AAMC Task Force. AAMC June 2008. [www.aamc.org/publications](http://www.aamc.org/publications)
3. Technology Transfer: Administration of the Bayh Dole Act by Research Universities. U.S General Accounting Office report to congressional committees. GAO/RCED-98-126, 1998. [www.gao.gov/archive/1998/rc98126.pdf](http://www.gao.gov/archive/1998/rc98126.pdf)
4. Bekelman JE, Li Y, Cary P, Gross CP. Scope and Impact of Financial Conflicts of Interest in Biomedical Research: A systematic review. JAMA 289:454-465, 2003.
5. Campbell EG, Gruen RL, et al. A National Survey of Physician-Industry Relationships. New England J. Medicine 356:1742-50, 2007.
6. Campbell EG, Weissman JS, et al. Institutional Academic Industry Relationships. JAMA 298:1779-86, 2007
7. Brennan TJ, Rothman DJ, et al. Health Industry Practices That Create Conflicts of Interest: A policy proposal for academic medical centers. JAMA 295:429-33, 2006.

## **P&S COI Policies**

Support for Educational Activities, Including Meals: Support from commercial entities, including but not restricted to refreshments served at educational programs, must be for unrestricted educational use. To separate commercial funding from education, this support must be overseen by Department chairs - rather than by divisions or individual P&S Faculty. Each year, Departments must report, by Division, commercial donations received and how these funds were spent. The reports shall be submitted to the Vice Dean for Academic Affairs.

Commercial entities should not provide direct support for refreshments at educational activities at CUMC. To avoid contact with patients receiving clinical services, industry representatives or their agents may not attend educational activities when held in clinical areas where direct patient care is being given concurrently.

For non-CUMC educational activities occurring off-campus, such as conferences and professional meetings, P&S Faculty are strongly encouraged to follow similar standards of unrestricted educational support. Commercial support beyond a modest standard for expenses related to legitimate CME activities will require appropriate disclosure. Support beyond legitimate expenses may raise questions regarding a Faculty member's objectivity (see Travel below).

Gifts: Columbia P&S Faculty, trainees, and students may not accept gifts of any value from commercial entities, including cash. No display of materials bearing commercial logos is permitted in patient areas: clocks, pens, books, etc. Commercial support for faculty activities lacking direct professional relevance is considered a gift and therefore is not permitted. Faculty may accept gifts from patients if not actually or appearing to affect clinical care, though gifts may not be accepted in lieu of remuneration for billable services. Contributions to Columbia University or NY Presbyterian Hospital are not covered by this policy, and are subject to University and Hospital policies.

Consultation: P&S Faculty are obligated to comply with Columbia University's policy on conflict of commitment: a maximum of 20% of time may be allowed for outside consulting activity for full-time faculty, provided that the outside activity does not compromise obligations to the University (Faculty Handbook Appendix J). Consulting activities should have no objectionable influence on teaching, research or patient care activities (Faculty Handbook, Appendix L). Consulting activities include, but are not limited to individual compensation received in connection with an outside activity, including making commercially supported professional presentations, as well as providing expert testimony on behalf of industry.

Annual disclosure of all non-clinical and non-academic consultation is required for all significant financial support, defined as: the total annual net remuneration in the preceding or current calendar year that exceeds \$10,000 from any single commercial entity (per University definition). This threshold of significance includes all payments and loans to a faculty member or his/her immediate family (per University definition). It excludes payments to faculty for service on advisory committees or review panels for public or nonprofit entities. Reporting excludes relevant travel expenses (see below).

Continuing Medical Education (CME): CME presentations – and all associated materials - should be educational rather than geared towards marketing or promotional purposes. Therefore, content must be independent of commercial influence for presentation by or for P&S Faculty, trainees or students. Prior to presentation or publication, P&S Faculty must disclose relationships with relevant commercial entities to the CUMC CME Office and to their audiences. In accordance with current policy for Columbia-sponsored CME, where there is an acknowledged potential conflict of interest, the content to be presented or published must be reviewed by another P&S Faculty member(s) who is free of such a conflict and who will certify that it is free of commercial influence.

For non-Columbia CME, P&S Faculty must disclose relevant conflicts of interest to and abide by the management practices of those accrediting entities. Regardless of location or sponsor, P&S Faculty are responsible for the content of presentations and materials at all times.

Non-CME Presentations: All presentations must be of one's own materials, not those created or supplied by drug or device companies or their agents. Presentations should be for the purpose of education and not for marketing or promotion.

Travel: Commercial support of P&S Faculty travel is limited to payment for legitimate professional speaking and consulting engagements. Commercial support of travel should be reasonable and of a modest standard (i.e., not lavish). Travel must be in accordance with Columbia's Travel and Entertainment Policy. Commercial support of trainees for travel, awards and fellowships must be administered through their respective departments.

Speakers' Bureaus: Membership in a Speakers' Bureau is defined as an arrangement that involves approval by a sponsoring commercial entity or its agent to give a presentation concerning the entity's products or services. Due to concerns that marketing imperatives may at times conflict with intellectual independence, P&S Faculty are strongly discouraged from membership in a Speaker's Bureau for commercial entities or their agents. Should faculty engage in these activities, the content and format of their presentations, as with all other professional presentations, should be educational and independent of commercial influence and not for marketing purposes. Appropriate disclosure is required, as part of Consultation activities (see above).

Ghost Writing: P&S Faculty, trainees and students are prohibited from authoring or co-authoring articles written by employees of commercial entities, where their name or Columbia title is used without substantive contribution. If commercial employees are co-authors, they should be acknowledged as such. Any articles or other materials written in conjunction with commercial entities must include full disclosure of the role of each author, as well as other contributions or participation by such commercial entities. P&S Faculty authors who collaborate with commercial entities must retain maintain editorial independence at all times.

Inventions: Patents, royalty agreements and licensing must be disclosed as applicable on Columbia's annual COI forms and in accordance with University and federal intellectual property policies. For decisions where specific expertise of faculty could be critical, such ties

may require oversight rather than removal from the decision-making process. Financial ties to inventions need to be appropriately disclosed to trainees and patients.

Drug and Device Representatives: Drug and device representatives coming to CUMC shall have access to physicians and staff only by appointment. Representatives must register with their host P&S Faculty member(s) in advance and wear badges identifying themselves as commercial agents (not just “visitors”). To avoid direct contact with patients, their family members or other accompanying individuals, drug representatives are not allowed in areas where direct patient care is being given. If demonstrations by commercial representatives (or their agents) are needed solely for device training, representatives should be clearly identified to staff and to any patients involved in that training, with practices that are HIPAA compliant, and patients’ consent should be obtained for involvement of commercial personnel.

Drug and Device Samples: Samples are solely for patient use, not for personal use by P&S Faculty or staff. Sample storage, access and distribution by faculty practitioners must be compliant with applicable regulations and departmental policies for safe storage and administration of medications. P&S Faculty should avoid actual or apparent conflicts of interest with regard to use and distribution of samples. Drug or device information for patients should be appropriate to their own condition, objective, and deliberately distributed by P&S Faculty – e.g., not casually accessible in waiting rooms or other patient areas.

Voluntary faculty: Voluntary P&S Faculty (“Zero Salary Faculty”) must act in the best interests of their professional duties at P&S, including patient care, research and education. In this capacity, they should avoid any potential or perceived conflicts of interest.

*Effective date: January 1, 2009*