

NEW YORK MEDICAL COLLEGE

Policy on Interactions with the Pharmaceutical, Biotechnology, Medical Device, Hospital and Research Equipment and Supplies Industries

I. Introduction

Professionalism lies at the heart of medicine and inculcating the values associated with it in our present and future physicians is a primary responsibility of academic medicine. In order that the interactions with the Pharmaceutical, Biotechnology, Medical Device, Hospital and Research Equipment and Supplies Industries (collectively referred to as “Industry”) consistently reflect the principles of professionalism, New York Medical College (NYMC) shall strive to impart the qualities of professionalism both through teaching and through the professional behaviors of faculty and staff.

In a report on Industry funding of medical education issued by the Association of American Medical Colleges (AAMC) in June 2008, the AAMC aptly states: “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 report goes on to state that the AAMC “embraces the obligation of the profession to manage, through effective self-regulation, all real or perceived conflicts of interest” and “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.”

II. Purpose

The purpose of this policy is to establish guidelines for interactions with Industry representatives for faculty, staff, students, and trainees of NYMC. Interactions with Industry occur in a variety of contexts, including marketing, sales and acquisition of new pharmaceutical products, medical devices, hospital and research equipment and supplies onsite, on-site training of newly purchased devices, the development of new devices, educational support of medical students and trainees, and continuing medical education. Faculty and trainees also participate in interactions with Industry off campus and in scholarly publications. Many aspects of these interactions are positive and important for promoting the educational, clinical and research missions of NYMC. However, these interactions must be ethical, free from influence created by improper financial relationships with, or gifts provided by, representatives of Industry and cannot create conflicts of interest that could endanger patient safety, data integrity, the integrity of our education and training programs, or the reputation of either the faculty member or the institution.

III. Scope of Policy

- A. This policy applies to all NYMC faculty and staff in their activities at NYMC and at NYMC affiliated institutions and all NYMC students and trainees.
- B. While this policy addresses many aspects of Industry relationships, it supplements and does not supersede the NYMC *Code of Conduct and Conflict of Interest Policy* and the ORA *Conflict of Financial Interest Policy and Disclosure Forms* or other existing policies of institutions where NYMC faculty hold medical staff appointments.
- C. This policy applies to faculty, staff and student interactions with all sales, marketing, or other product-oriented personnel of Industry, specifically those individuals whose purpose is to provide information to clinicians about company products or services, whether or not such personnel are classified in their company in a "sales" or "marketing" capacity.
- D. Charitable gifts provided by Industry in connection with fundraising done by or on behalf of NYMC are not covered by this Policy.

IV. Definitions

The terms have the following meaning in this Policy:

"Industry" is defined as all pharmaceutical manufacturers, biotechnology companies, medical device and hospital and research equipment suppliers and their sales and marketing representatives.

"Gifts" means any gratuity, favor, discount, entertainment, hospitality, loan, forbearance, or other item of more than nominal monetary value. It includes services as well as gifts of transportation, local travel, lodgings and meals, whether provided in-kind, by purchase of a ticket, payment in advance or reimbursement after the expense has been incurred.

V. Statement of Policy

It is the policy of NYMC that educational, clinical and research activities must be free from influence created by improper financial relationships with, or gifts provided by, representatives of Industry and that thereby interactions with Industry shall be conducted so as to avoid or minimize real or perceived conflicts of interest. When conflicts of interest do arise they must be addressed appropriately and consistent with the specific limitations as described in this Policy.

VI. Specific Limitations on Industry Interactions

This policy addresses the following types of interactions with Industry:

A. Gifts

Faculty, staff, students and trainees of NYMC shall not receive gifts from Industry.

B. Compensation

1. Faculty, staff, students and trainees of NYMC may not accept compensation from Industry for listening to a sales talk/presentation by an Industry representative.
2. Faculty, staff, students and trainees of NYMC may not accept compensation from Industry for prescribing or changing a patient's prescription.
3. Faculty, staff, students and trainees of NYMC must consciously and actively divorce academic and clinical care decisions from any real or perceived benefits expected from Industry. It is unacceptable for educational, research and patient care decisions to be influenced by the possibility of personal financial gain.
4. Faculty, staff, students and trainees of NYMC may not accept compensation, including the defraying of costs, for simply attending a Continuing Medical Education ("CME") or other activity or conference (that is, if the individual is not speaking or otherwise actively participating or presenting at the event).

C. Samples

Distribution of samples should comply with Federal Drug Administration guidelines. Faculty, staff, students and trainees of NYMC should avoid direct distribution of samples.

D. Site Access by Industry Sales and Marketing Representatives

1. Industry sales and marketing representatives are not permitted in any patient care areas except to provide in-service training on devices and other equipment and then only by appointment. (Note: The requirements of existing vendor policies at NYMC's affiliated hospitals continue in full force and effect.)
2. Industry sales and marketing representatives are permitted in non-patient care and non public areas by appointment only. Appointments will normally be made for such purposes as:

- a. In-service training of NYMC personnel for research or clinical equipment or devices already purchased.
 - b. Evaluation of new purchases of equipment, devices, or related items.
3. Appointments to obtain information about new drugs in the formulary will normally be issued by the hospital or medical center's pharmacy.
 4. Appointments may be made on a per visit basis or as a standing appointment for a specified period of time, at the discretion of the faculty member, his or her division or department, or designated hospital or medical center personnel issuing the invitation and with the approval of appropriate hospital management. Involvement of students and trainees in such meetings should occur only for educational purposes and only under the direct supervision of a faculty member.

E. Continuing Medical Education ("CME")

1. All requests for CME Industry support and receipt of funds must be coordinated and overseen by the NYMC Continuing Medical Education Office.
2. Faculty, staff, students and trainees of NYMC should be aware of the Standards for Commercial Support of the Accreditation Council for Continuing Medical Education (ACCME). They provide useful guidelines for evaluating all forms of Industry interaction, both on and off campus and including both NYMC - sponsored and other events. The Standards may be found at <http://www.accme.org/>.
3. All CME education events and programs sponsored or supported by Industry must be offered only by ACCME-accredited providers and must be compliant with ACCME Standards for Commercial Support whether or not CME credit is awarded.

F. Participation in Industry-Sponsored Program

1. Faculty, staff, students and trainees of NYMC should evaluate very carefully their own participation in programs (such as meetings and conferences) that are fully or partially sponsored or run by Industry because of the high potential for perceived or real conflict of interest. This provision does not apply to meetings of professional societies that may receive partial Industry support, meetings governed by ACCME Standards, and the like.

2. Faculty, staff, student and trainees of NYMC who attend (but do not actively participate in (e.g., by serving as a speaker, organizing the meeting) programs accredited by the ACCME supported in part or in whole by Industry are prohibited from:
 - a. Accepting payment for attendance at Industry-sponsored meetings; and/or
 - b. Accepting gifts from Industry at such events.

Such faculty, staff, student and trainees must timely disclose to their department heads when participating in such programs.

3. Faculty, staff, students and trainees of NYMC who actively participate in programs accredited by the ACCME supported in part or in whole by Industry (e.g., by speaking, organizing the meeting) are required to:
 - a. Provide prior timely notice to their department heads before participating in such programs;
 - b. Accept only payments at fair market value for such active participation;

and,
 - c. Observe all of the following guidelines:
 - i. Any financial support provided to the NYMC faculty, staff, student or trainee by Industry is fully disclosed by the meeting sponsor;
 - ii. The meeting or lecture content is determined by the speaker and not the Industry sponsor;
 - iii. Speakers are expected to provide a fair and balanced assessment of therapeutic options and to promote objective scientific and educational activities and discourse;
 - iv. The NYMC participant is not required by an Industry sponsor to accept advice or services concerning speakers, content, etc., as a condition of the Industry sponsor's contribution of funds or services;
 - v. The speaker/lecturer discloses that the content reflects individual views and not the views of NYMC, or its affiliated hospitals; and

- vi. The use of the NYMC name in a non-NYMC event is limited to the identification of the individual by his or her title and affiliation.

G. Industry-Sponsored Scholarships and Other Educational Funds for Students and Trainees

1. Industry support of students and trainees should be free of any actual or perceived conflict of interest, must be specifically for the purpose of education and must comply with all of the following provisions:
 - a. The respective Dean of the NYMC school involved (or his/her designee) shall evaluate and select the recipient of such funds with no involvement by the Industry donor;
 - b. All scholarships or other educational funds from Industry are provided to NYMC and not directly to the student or trainee;
 - c. The department, program or division at NYMC has determined that the funded conference or program has educational merit; and
 - d. The recipient is not subject to any implicit or explicit expectation of providing something in return for the support, i.e., a “quid pro quo.”

H. Meals

With the exception of food provided in connection with *ACCME*-accredited programming and in compliance with *ACCME* guidelines, meals or other types of food directly funded by Industry are considered personal gifts and will not be permitted or provided at NYMC. All physicians, faculty, staff, students and trainees of NYMC shall adhere to this standard of behavior whether on-site at or off-site from NYMC and its affiliated hospitals.

I. Professional Travel

Physicians, faculty, staff, students and trainees of NYMC may not accept travel funds from Industry other than for legitimate reimbursement or contractual services.

J. Ghostwriting and Disclosure of Relationships with Industry

1. Physicians, faculty, staff, students and trainees of NYMC are prohibited from publishing articles under his/her own name or permitting other professional presentations of any kind, oral or written, that are written in whole or material part by any party, Industry or otherwise.

2. In scholarly publications, physicians, faculty, staff, students and trainees of NYMC must disclose their related financial interests in accordance with the International Committee of Medical Journal Editors (<http://www.icmje.org/>).
3. Faculty with supervisory responsibilities for students, residents, trainees or staff should ensure that a faculty's conflict or potential conflict of interest does not affect or appear to affect his or her supervision of the student, trainee, or staff member.
4. Faculty, staff, students and trainees of NYMC having a direct role making institutional decisions on equipment or drug procurement must timely disclose any financial interest they or their immediate family have in any particular manufacturer of pharmaceuticals, devices, or equipment, or any provider of services before the purchasing decision is made and refrain from any involvement in purchasing decisions relevant to the conflicting interests. Such financial interests include equity ownership, compensated positions on advisory boards, a paid consultancy, or other forms of compensated relationship. They must also disclose any research or educational interest they or their department have that might substantially benefit from the purchasing decision. In the event that an individual's expertise is reasonably necessary in the evaluation of any product, that individual's financial ties to any manufacturer of that or any related product must be timely disclosed to those charged with the responsibility for making the purchasing decision.

K. Board of Directors, Advisory Board, and Consulting Relationships

Activities or titles that constitute or imply managerial or supervisory responsibility such as CEO, Vice President, Director, Manager, Scientific Officer, Chief, etc., generally create real or perceived conflicts and are thereby not allowable as consulting relations. While appointments and service in Industry scientific or technical advisory boards or councils are different from managerial and supervisory roles and titles, these appointments can also create real or perceived conflicts of interests if they reasonably interfere or tend to interfere with or are inconsistent with the performance of the individual's work or responsibilities for the College. Consulting arrangements providing for guaranteed compensation without specific, associated duties are considered "gifts" and are thus prohibited. In order to avoid the appearance of impropriety or gifts disguised as consulting arrangements, all consulting arrangements with Industry, including appointments on scientific or technical advisory boards or councils, must timely be disclosed to ensure that the consulting contract identifies specific tasks and deliverables and contains payment provisions that are at fair market value and consistent with the assigned tasks.

VII. Distribution, Notification and Procedures for Violations of This Policy

A. Distribution and Notice

This policy shall be distributed to all faculty, staff, students and trainees of the College prior to its effective date and thereafter annually. This policy shall also be posted on the NYMC website.

B. Procedures for Alleged Violations

Any alleged violations are to be reported in a timely manner to the individual's Dean of the NYMC school involved, the individual's department head, or to the NYMC's Institutional Compliance Officer or Compliance Director. All reports of alleged violations shall be investigated as appropriate under the direction of NYMC's Institutional Compliance Officer or Compliance Director, in consultation with the individual's Dean of the NYMC school involved or the individual's department head.

VIII. Interpretation

Questions concerning the interpretation or applicability of this policy should be directed to the Office of the General Counsel.

This Policy was reviewed by the Institutional Compliance Committee of the College on December 9, 2009, and approved on December 16, 2009, by, respectively, the Audit Committee of the Board of Trustees and by the Board of Trustees of New York Medical College. It is effective as of January 1, 2010.