POLICY: Faculty, Clinical Staff and Trainee Interactions with a Health-related Industry: Pharmaceutical, Medical Device and Other Manufacturers or Marketers of Healthcare Products and Services

A. OVERVIEW

Relationships among physicians and industry, i.e. pharmaceutical, biotechnology, and medical device companies, help drive innovation in patient care and contribute to the economic well-being of the community to the ultimate benefit of patients and the public. However, an increasingly urgent challenge for both medicine and industry is to devise ways to preserve strong, productive collaborations at the same time that they take clear effective action to prevent relationships that damage public trust and tarnish the reputation of both parties. Therefore, NYU Winthrop Hospital medical staff embraces the following principles:

1) All faculty, clinical staff and trainees must be committed to maintaining the highest ethical and professional standards in order to safeguard and successfully carry-out our missions of patient care, medical education and research.

2) The hospital’s ability to assess and manage real or perceived conflicts of interest of our faculty, clinical staff and trainees with industry must be done in a consistent manner and in recognition of our ethical obligations to our patients and to our profession.

B. DEFINITIONS

1) **Health Related Industry, or Industry:**
   For purposes of this policy, refers to the manufacturers or marketers of healthcare products and services, including pharmaceutical, medical device and other ACCME-defined commercial interests that market, sell, or distribute health care products or services consumed by, or used on, patients.

2) **Conflict of Interest:**
   A set of circumstances that creates a risk that professional judgment or actions regarding a primary interest will be unduly influenced by a secondary interest (source-Institute of Medicine).

3) **Faculty:**
   Comprises all full and part time employed medical staff of NYUWH, residents, physician assistants (PAs), nurse practitioners (NPs), nursing, pharmacy and all other allied health clinical staff serving as teachers and educators and who are employed by the hospital.

4) **Trainees:**
   Includes all residents, fellows, medical students, PA, NP, nursing and all other students completing a formal course of training in the health professions at NYUWH.
5) **Campus:**
For purposes of this policy, includes all clinical care settings where employed Winthrop practice: NYUWH-owned inpatient and ambulatory care facilities as well as all affiliated practice sites. NYUWH trainees who are included in this policy are expected to adhere to policy standards while rotating to affiliated institutions.

6) **Clinical Staff:**
Any other individuals including PAs, NPs, pharmacists, nurses and other allied health professionals.

7) **Gifts:**
Anything of value that is not reasonable compensation for bona fide services. This includes meals, money, entertainment, gift cards, and any other products, services or subsidies that are not specially authorized by provisions of this policy.

C. GUIDELINES

1. **Faculty and Clinical Staff Interactions with Health-Related Industry**

   a) Faculty and clinical staff should model behavior consistent with ethical guidelines developed by responsible professional organizations (American Medical Association, Accreditation Council for Continuing Medical Education and American Nurse Credentialing Center) regarding relationships between physicians and industry. Professionalism requires that the same standards apply off-site as well as on the campus.

   b) Regardless of venue or sponsorship, faculty must present only objective, unbiased and evidenced-based content, consistent with established norms and expectations of the accrediting bodies of our educational programs, in particular, the LCME, ACGME, ACCME, and the ANCC.

   c) Faculty may not receive honoraria for activities given on campus or sponsored by NYUWH, including NYU Winthrop Hospital-affiliated ambulatory sites, during usual working hours or in the course of usual working responsibilities.

   d) Faculty and clinical staff are not to utilize NYU Winthrop Hospital resources to support or promote after-hours lectures or other industry-driven activities, unless the program is formally accredited and sponsored directly by NYU Winthrop’s CME-CE program.

   e) Faculty are to discourage the attendance of trainees and clinical staff at activities off-campus sponsored by industry, or at educational events off campus sponsored by industry, that are clearly promotional, and that are not sponsored by an ACCME or ANCC accredited provider of continuing health professional education, nor are a required component of one’s formal training program.

   f) Faculty and clinical staff (if applicable) may serve as consultants to commercial support companies for clearly defined professional services. (See section on Speakers Bureaus and Advisory Boards.) These arrangements must be disclosed to NYUWH Corporate Compliance and be reported on annual faculty disclosure forms.

   g) Faculty and clinical staff must disclose to audiences all relevant financial relationships with industry that might constitute to a real or perceived conflict of interest when a speaker at CME-CE accredited activities.
2. **Trainee Interactions with Health-Related Industry Representatives**

   a) Trainees may not organize, promote, or attend, either on-campus or off-campus, industry-sponsored activities unless permitted by the Program Director or Clerkship Director. Educational activities must be organized in concert with the CME-CE Office.

   b) Trainees may not attend detailing lunches either on or off campus without a faculty member present who is required to do an academic critique.

   c) Trainees may not engage in any detailing activities (including computer based detailing), either on or off campus, for which they receive gifts or payments.

   d) Trainees may not receive payments for participation in lectures or detailing programs including those described as “peer groups”, “advisory boards”, dinner lectures, and the like.

   e) Trainees may not accept gifts from industry, whether or not they are related to professional activities. Educational gifts made directly to a Division or Department may be distributed to trainees if the item is unbranded, and the Division or Department gives the industry representative no consideration for the gift.

   f) Trainees and Chief Residents may neither organize nor attend industry sponsored social events, even if associated with educational activities.

3. **Pharmaceutical Representatives, Device Manufacturer Representatives, and Technology Consultants**

   a) **Inpatient Settings**

   The role of pharmaceutical representatives in the hospital is limited to providing technical information to the Department of Pharmacy and Pharmacy and Therapeutics Committee. Promotional activities of these representatives do not serve the operational or educational interests of the institution.

   The role of device manufacturer representatives (e.g., surgical, radiological, cardiological), whose mission is to promote products, is distinct from that of the device technology consultant, who may often have a legitimate, if not essential, role in providing technical support to users of these devices. It is the intent of this policy to eliminate the non-essential/non-technical activities of device representatives while ensuring continued, necessary technical support for instrumentation in use at NYU Winthrop.

   1) **Pharmaceutical Representatives**

      a) Must comply with Department of Pharmacy Policy regarding pharmacy detailers.

      b) Representatives may not use hospital infrastructure (bulletin boards, fax machines) for promotion of programs not accredited by the ACCME.
c) Representatives may not loiter in the Health Sciences Library, hospital lobby or elsewhere on campus for the purpose of contacting physicians.

d) Representatives may not engage in any detailing, promotional, or educational activities on the inpatient floors or in any clinical area. Any representative found in a patient care area, in breach of hospital policy, will be removed and repeat offenders will be denied access to NYU Winthrop Hospital and their companies will be notified of violation of hospital policy.

e) Representatives may not, at any time, promote or offer professionally non-relevant activities, such as raffles, sweepstakes, contests and tickets to cultural or sporting events.

f) Representatives may meet with the chief of service or designee by appointment.

g) Representatives may not provide meals other food items under any circumstance.

h) Representatives may not offer scholarship, grants or funds directly to any trainee or member of the clinical staff.

2) Device Manufacturer Representatives

a) Representatives may not use hospital infrastructure (bulletin boards, fax machines) for promotion of programs not accredited by an ACCME accredited organization.

b) Representatives may not loiter in the Health Sciences Library, hospital lobby or elsewhere on campus for the purpose of contacting physicians.

c) Representatives may not engage in any detailing or promotional activities on the inpatient floors or in any clinical area. Any representative found in a patient care area, in breach of hospital policy, will be removed, and repeat offenders will be denied access to NYU Winthrop Hospital. Representatives may not use their technical support based access to physicians for sales, promotional or marketing activities.

d) Representatives may not, at any time, promote or offer professionally non-relevant activities, such as raffles, sweepstakes, contests and tickets to cultural or sporting events.

e) Representatives may meet with the chief of service or designee by appointment.

f) Representatives may not provide meals and other food items under any circumstances.

g) Representatives may not offer scholarship, grants or funds directly to any trainee of member of the clinical staff.

3) Device Manufacturer Technology Consultants

a) Device consultants may be permitted in clinical areas only by specific request of an attending physician and only for direct technical support of the product/device.
b) Device consultants may not be present during any patient care interaction unless there has been prior disclosure to and consent by the patient.

c) Device consultants providing technical assistance must be certified by their employer to provide requested device training and meet requisite Employee Health requirements.

d) Device consultants must comply with all departmental policies (e.g., Policy on Perioperative Services).

e) Consultants’ in-services and related programs must be organized by and attended by at least one faculty physician.

f) Device consultants may not use their technical support based access to physicians for sales, promotional or marketing activities.

b) **Ambulatory Practice Settings**

Presentations by pharmaceutical or device representatives may have specific value in terms of assisting faculty in educating trainees in analysis of promotional material and in recognizing marketing techniques. Presentation by industry representatives and attended by trainees must conform to the following:

a) Presentations by industry representatives must be organized and directed by the chief of service or designee.

b) Attendees must include at least one faculty physician.

c) Representatives must make promotional materials to be used during a meeting available to the faculty preceptor prior to the meeting in a timeframe acceptable to the preceptor.

d) A faculty member must be prepared to discuss the promoted material in an objective and evidence-based fashion or assign this responsibility to a trainee. This preparation may include critical review of the promotional material, presentation of additional or refuting studies, referencing the promoted information with consensus panel statements, position papers, etc. (See attached guidelines.)

e) No food items or gifts are permitted in any ambulatory practice setting where employed NYU Winthrop faculty practice.

4. **Gifts, Travel to Conferences, Meals and Entertainment**

Gifts from health related industry, regardless of monetary value, are intended to influence physician behavior and have been found to be effective in doing so. Meals or other food items are gifts whether or not they are associated with a professional gathering or other activity and whether they are provided on site or off campus.

a) Faculty, trainees and clinical staff may not accept meals or other food items from pharmaceutical or device manufacturers.

b) Faculty, all trainees, and clinical staff may not accept gifts of any monetary value from pharmaceutical or device manufacturers, whether or not they have direct educational value or are related to clinical care. These include, but are not limited to, books, pens, notepads,
stethoscopes, penlights, and medication samples (see section on medication and product samples).

c) Faculty, all trainees, and clinical staff may not accept free or reduced price entry to any entertainment event from pharmaceutical or device manufacturers.

d) These prohibitions include paid travel and registration fees to educational conferences, meals, and other hospitality, even if offered after work hours and at off-campus venues, such as industry-sponsored dinner lectures, national conferences, etc.

Exceptions

Unrestricted grants from industry to support educational objectives of an academic division or department are not considered gifts if they do not influence or have the potential to influence physician, resident or clinical staff behavior. Such grants are permitted under the following criteria:

a) Funds offered by industry are acceptable for the following activities: for CME-CE accredited courses, symposia, grand rounds; for ACGME-accredited residency or fellowship educational activities, including scholarships or other types of support for attendance at professional conferences; for allied health educational activities; for mandatory travel to educational conferences required for principal and co-principal investigators of funded scientific research projects; receipt of scientific, clinical, or other achievement awards, even if funded or named by industry. Such awards must be based on professional merit and must be reviewed and approved by the appropriate Department Chair.

b) Funds must be deposited in a transparent NYU Winthrop educational account and charges against said funds must be drawn against this account in accordance to NYUWH policy.

c) For these funds to be considered unrestricted, use of the funds must be fully independent of industry influence and the party providing the funds may receive no consideration for the grant beyond a simple acknowledgement of the grant for transparency. For CME activities, grants from industry must comply fully with the ACCME’s Standards of Commercial Support. (www.accme.org)

5. Medication and Product Samples

Medication and other product sampling are marketing activities designed to increase the use of these products and to gain access to prescribers in order to influence their clinical practice. Although the availability of samples can sometimes be advantageous to patients, these benefits can often be otherwise achieved without influence on clinicians. Moreover, the availability of samples can raise patients’ overall drug costs through the increased likelihood of having prescribed a non-generic medication, even when acceptable generic alternatives are available. Use of drug samples can only be justified when patient benefit is significantly served, since the availability of samples has the potential to unduly affect physician prescribing.
a) Prescription medication samples dispensed from the office practices associated with NYU Winthrop Hospital in which faculty practice and/or house staff train, are subject to the following conditions:

1) Practices may stock branded medication samples only for which generic or clinically equivalent medication are unavailable by prescription.
2) The clinical Division Chief, or designee must determine which medications, if any, meet the criteria in (1) above.
3) The procurement of medication samples must not be predicated on a face-to-face interaction between pharmaceutical detailers and clinical staff.
4) The availability of medication sample must not alter the clinician’s selection of medication.
5) Patient benefit must be the primary and over-riding motivation for selecting the product sample.
6) Appropriate medication information must be distributed to the patient with the sample.
7) Any practice that decides to dispense samples must follow the requirements of the N.Y. State Board of Pharmacy.

b) Medications that are available over-the-counter may not be dispensed from office practices.

1) Product samples that are available over-the-counter (e.g., baby formula, nutritional supplements) may not be dispensed from office practices.
2) Neither faculty nor trainees may accept sample medications or products for personal or family use, as these are considered gifts and are prohibited.
3) Practices may accept product-free teaching tools (e.g., meter dose inhalers) from pharmaceutical representatives for the purpose of benefiting their patients.
4) All offices and clinical care areas are to be free of any materials that bear the name of a particular product or company (e.g., tissue boxes, note pads, etc.). An exception may be materials used for purposes of patient education. They may be used only if comparable materials are not available from non-industry sources.

6. Advisory Boards and Speakers Bureaus

Interaction between faculty and industry is appropriate and even desirable under certain circumstances. These include participation in industry boards of directors, scientific advisory boards and consulting relationships.

a. Advisory Boards

Faculty may serve on advisory boards provided:

1) There are clear written agreements on scope of services.
2) Compensation is commensurate with the services.
3) The agreements comply with NYUWH corporate compliance requirements and applicable law.
4) Compensation is disclosed to NYUWH.
b. **Speakers Bureaus**

Faculty are encouraged to participate in accredited CME programs. Faculty **may not** participate in, or receive compensation for talks through a Speakers’ Bureau.

.7. **Required GME Education on Conflicts of Interest, Professionalism, Ethics and Physician Relationships with Industry must address:**

   a) Pharmaceutical industry marketing techniques and evaluation of promotional literature.
   b) Recognition of clinically relevant and irrelevant drug information.
   c) Assessments of the validity of the presented information and identification of omitted information.
   d) Ethical issues/conflicts of interest raised by interactions with industry.

8. **Monitoring and Enforcement of Policy**

   a) Enforcement of this policy shall be the responsibility of the Chief of each division, who shall be responsible to the Chair for such monitoring and enforcement. The Chairs shall report annually to the Chief Academic Officer (CAO).

9. **Disclosure and Attestation Process**

   a) All industry-related activities and income shall be reported annually to Department Chairs, the CAO and the Compliance Committee. All faculty serving as planners of educational content, speakers at accredited or un-accredited educational activities, and as teachers of residents and/or students, must complete and sign an annual CME-CE Faculty Planner/Speaker Disclosure Form in addition to the NYU Winthrop Corporate Compliance Disclosure Form.