

Summary
SUNY Upstate Medical University
Policy on Relations with the
Pharmaceutical, Medical Device, and Biotechnology Industries

The mission of SUNY Upstate Medical University is to improve the health of the communities we serve through education, biomedical research, and health care. Clinicians have a primary responsibility to work for patients' welfare. Researchers are dedicated to furthering scientific biomedical understanding in ways that can be translated into products and techniques that benefit society. To achieve these ends, SUNY Upstate's faculty, staff, and students interact and, at times, partner with the pharmaceutical and medical device industries.

This policy establishes expectations for behavior in relations with the pharmaceutical, medical device, and biotechnology industries (hereafter referred to as Industry) in accordance with the expressed values of SUNY Upstate Medical University. It is intended to guide interactions with Industry so that institutional and professional integrity is maintained while we care for patients, teach clinicians, scientists, and students, and carry out biomedical research. We also interact with other industries that are not named specifically in this policy. With regard to those interactions, we should maintain a standard of reasonable conduct that is consistent with the intent of this policy.

Covered Individuals: This policy applies throughout SUNY Upstate to all employees (including faculty, staff, residents, fellows, others in training), students, employees of the Research Foundation of the State University of New York, employees of MedBest, and members of the SUNY Upstate Council, who shall be known as covered individuals, unless otherwise noted.

This policy augments existing laws, including the New York State Public Officers Law; state, SUNY, and campus policies; and negotiated agreements. Nothing in this policy shall take precedence over existing laws, policies, and negotiated agreements with any union of employees. Individual departments and units shall review their policies and revise them if necessary to ensure that they are consistent with this policy.

Section 1. Relations with Industry in Patient Care and Education

1. Detailing by Industry representatives

a. Industry representatives must make an appointment to see Upstate personnel and are allowed only in non-patient care areas and nonpublic areas. Exception: Device representatives are allowed in patient care areas to provide in-service training or assistance on devices and equipment, with prior disclosure to and consent by patient.

b. Contact with residents, fellows, students, and others in training by Industry representatives should occur only for educational purposes under the supervision of a faculty member.

2. Institutional purchasing decisions; covered individuals with financial interests

a. Covered individuals with any financial interest in Industry, or whose immediate family member (spouse, domestic partner, or child) has such an interest, must disclose it to their supervisor and the COI Officer and withdraw from involvement in purchasing decisions relevant to the conflicting interests.

b. If an individual's expertise is necessary in evaluating a product, but that person also has financial ties to any manufacturer of that or any related product, the ties must be disclosed and only written testimony will be accepted for consideration in deciding whether the product will be adopted.

c. Those who request that a given drug, device, or product be adopted by the institution must disclose any financial interests they have in this product.

3. Gifts and meals

a. Employees and students are prohibited from accepting gifts of any kind from representatives of Industry. Gifts are defined as anything of monetary value, regardless of amount, and include, but are not limited to, pens, pads, stethoscopes, textbooks, money, services, favors, discounts, food, conference fees, lodging, travel to conferences, entertainment, or other hospitality.

b. Educational materials for patients, students, and others that are developed by Industry may be accepted if they are the best source of such materials available and are for the purpose of education. They may not be accepted if it is evident that they are primarily for the purpose of selling a product. Also, written materials are permitted for products for which manufacturers' information and instructions are required.

c. Travel funded by Industry to be trained on equipment already purchased by or approved for use at Upstate, is not considered a gift and is permitted. Provision for such travel should be included in the contract or memorialized in some other manner. Travel funded by Industry to evaluate equipment not yet purchased by Upstate is allowed if the equipment to be purchased is included in the open bid process. For sole-source vendors, the purchasing entity (e.g., University Hospital, medical service group) should pay for the travel.

4. Free drug samples

a. Samples may be dispensed only to patients being cared for at the practice site and who meet one of the following conditions:

- are medically indigent,
- have no prescription coverage for extraordinarily expensive agents
- temporarily do not have access to other pharmacy services
- a short trial (1 week or less) of the medication is necessary to determine whether

it has the desired effect or the medication needs to be changed before taking the prescription to the pharmacy and thus, thus avoiding unnecessary costs.

b. The Pharmacy Department will conduct routine on-site inspections and annual review of written procedures.

5. Industry-sponsored speakers' bureaus

a. Industry-sponsored speakers' bureaus are defined as follows. Industry hires faculty speakers to deliver promotional talks, using Industry-prepared and approved presentations. These talks are confined to FDA-approved product safety and efficacy discussions and approved disease-state education. By the nature of their content and origin of their authorship, such talks do not qualify for CME certification.

b. Participation in Industry-sponsored speakers' bureaus by covered individuals is prohibited. (Covered individuals may provide certified CME talks.) Covered individuals or Upstate departments may not sponsor or promote Industry-sponsored speakers' bureau talks, and Industry-sponsored speakers' bureau talks are prohibited on University premises.

6. Continuing education - Upstate already adheres to the standards of the Accreditation Council for Continuing Medical Education (ACCME).

a. The following applies to all continuing education (CE), whether it is continuing medical education (CME) or CE in other disciplines. SUNY Upstate units (e.g., departments, colleges, University Hospital) may accept funds from Industry for CE, but Industry may not specify the content or the speakers. Industry may request the overall topic, such as a condition or disease state (e.g., epilepsy, hypertension, lung cancer).

b. All CE events hosted or sponsored by SUNY Upstate must comply with ACCME (or comparable) standards, whether or not CE credit is awarded.

c. Industry funding may not be used to support meals or social activities related to continuing education.

d. Training programs designed solely for sales or marketing are prohibited.

f. Industry support for CE in the form of donated funds shall be recognized in a manner that does not promote a particular product.

Section 2. Relations with Industry in Research and the Training of Scientists

This section applies to all covered individuals, as well as voluntary faculty, who are involved in the design, conduct, or reporting of research and their immediate family members (spouse, domestic partner, and children).

1. Gifts from research sponsors

a. Gifts to members of a research team from research sponsors are prohibited.

b. Travel related to conducting clinical research is not considered a gift.

2. Use of University resources including privileged information

a. Privileged information should not be used for personal gain

b. The Upstate Medical University name should not be used in a manner that implies that the University is associated with, sponsors, or endorses an external activity.

3. Purchasing, contracting, other business transactions on behalf of the University

Activities that involve Upstate Medical University and an entity in which an individual has a personal financial interest must have prior review and approval.

4. Intellectual property

All Upstate inventors and developers of intellectual property must declare their personal financial interests, and those of their family (spouse, domestic partner, or child), prior to the start of the licensing process.

5. Individuals on University review panels (such as the IRB, IACUC, Research COI Committee, purchase evaluation committees)

All panel members will submit a Conflict of Interest (COI) Declaration Form (and, if necessary) COI Disclosure Form at the time of their appointment.

6. Research and sponsored projects

All personnel involved in conduct or reporting of Industry-sponsored research must report any possible personal conflict of interest related to the sponsored research.

7. Ghostwriting is prohibited.

Section 3. Personal Financial Interests of University Leadership in Industry

Institutional leaders and those making key purchasing decisions are required to divest themselves of all investments or other financial relationships with Industry. Individuals included:

1. President, SUNY Upstate
2. Vice Presidents of the University
3. Chief Executive Officer, University Hospital
4. Deans of Colleges of Graduate Studies, Health Professions, Medicine, Nursing
5. Chair of the Pharmacy and Therapeutics Committee, University Hospital
6. Chair of the Institutional Review Board, the IRB Administrator, and Chief Compliance Officer for Research
7. Chair, Values Analysis Committee, University Hospital; Values Analysis Coordinator

Investments and relationships that are included:

1. Equity interests in Industry, but does not include mutual funds or similar investment vehicles over which the owner does not have direct control of purchasing or selling;
2. Acceptance of consulting fees, advisory board fees, honoraria, “in kind” compensation, gifts, or other remunerations from an Industry entity;
3. Service as an officer, director, or board member of an Industry entity;
4. Service on the scientific advisory board of a commercial sponsor of research conducted at Upstate.

Section 4. Conflict of Commitment

Conflicts of commitment arise when either the amount of time an individual spends on external efforts interferes with his or her ability to meet responsibilities to Upstate or the external efforts adversely affect the quality of their efforts in fulfilling obligations to Upstate.

- Consulting and other outside activities must be pre-approved by the relevant supervisor and reviewed on an annual basis.

- A maximum of 36 days annually for such activities may be allowed, *provided the individual continues to fulfill 100% of his/her commitments and professional obligations to the University.* (Instances of exceeding the time limit guidelines should be exceptional and may be granted only if approved by the department chair in consultation with the dean of the relevant college or unit head in University Hospital in consultation with the CEO of UH.)

Section 5. Policy Implementation

A **Conflict of Interest (COI) Officer** will (1) oversee the implementation, evaluation, and revision of this policy; (2) respond to questions about this policy and provide authoritative guidance as to how the policy applies to particular situations; (3) receive and evaluate declarations of conflicts of interest and make recommendations regarding them; (4) monitor compliance with this policy; (5) serve ex officio, with vote, on the Research Conflict of Interest Committee; (6) ensure that this policy is accessible to all Upstate personnel and the public through the Upstate Medical University website.

Disclosures

- 1. All covered individuals must disclose to the COI Officer any financial arrangements with Industry** that exceed \$1,000 from any single company annually.

- 2. Disclosure of relationships with Industry to students**

Covered individuals in a teaching capacity should inform their students and other learners of their relationships with Industry. This may be done at the beginning of a course or session or other appropriate time. In situations that are transient or inconvenient (e.g., patient rounds), the teacher should use his/her discretion in informing students, being guided by the relevance of the relationship with Industry to the situation at hand.

- 3. Issues related to relations with Industry in research**, including disclosure of relationships, the role of the Research COI Committee, the review process, reporting of conflicts to outside agencies, and the appeal process will be found in the full policy.