

NOTICE OF PROPOSED REGULATION

Date: May 8, 2012

REGULATION TITLE:

College of Medicine Policy on Pharmaceutical, Medical Device
and Biotechnology Industry Conflicts of Interest and Industry/
Academic Relations

REGULATION NO.:

5.0764

SUMMARY: This regulation sets forth the College of Medicine policy on conflicts of interest with regard to the pharmaceutical, medical device, and biotechnology industries and their representatives (pharmaceutical industry). The policy applies to all employees and appointees of the University of Florida College of Medicine and is supplemental to University Regulation 1.011. The subject matters regulated are listed in the regulation, which includes a Web site where the detailed requirements, as in effect at any particular time, will be set forth. As currently existing, that policy provides that, in general, College of Medicine personnel may not accept gifts from the pharmaceutical industry, including without limitation the receipt of pharmaceutical samples and educational materials. Generally College of Medicine personnel may not accept meals or other gifts of food for themselves or others if sponsored or provided by the pharmaceutical industry and may not accept travel funds from the pharmaceutical industry to attend a meeting or conference except as set forth in the policy. They may not accept scholarships or fellowships directly from the pharmaceutical industry. Access by the pharmaceutical industry to College of Medicine premises is restricted. The conditions under which College of Medicine personnel may participate in pharmaceutical industry-sponsored events, including CME, are set forth. The specific conditions under which College of Medicine personnel may participate in, attend, or be a compensated speaker at off-site conferences and meetings sponsored by the pharmaceutical industry are detailed. College of Medicine personnel are not permitted to participate in pharmaceutical industry-sponsored speakers bureaus. Professional presentations and writings must have appropriate authorship attribution.

AUTHORITY: BOG Regulation 1.001

COMMENTS CONCERNING THE PROPOSED REGULATION SHOULD BE SUBMITTED WITHIN 14 DAYS OF THE DATE OF THIS NOTICE TO THE CONTACT PERSON IDENTIFIED BELOW. The comments must identify the regulation you are commenting on.

THE PERSON TO BE CONTACTED REGARDING THE PROPOSED REGULATION IS: Rebecca J. Holt, Senior Administrative Assistant, 123 Tigert Hall, Post Office Box 113125, University of Florida, Gainesville, Florida 32611, 352-392-1358 office, 352-392-4387 facsimile, regulations@ufl.edu.

NAME OF PERSON WHO APPROVED THE PROPOSED REGULATION: David Guzick, Senior Vice President for Health Affairs

THE FULL TEXT OF THE PROPOSED REGULATION IS ATTACHED TO THIS NOTICE.

REGULATIONS OF THE
UNIVERSITY OF FLORIDA

5.0764 College of Medicine Policy on Pharmaceutical, Medical Device, and
Biotechnology Industry Conflicts of Interest

(1) Definitions. The following definitions apply to this regulation:

(a) “COM” means the University of Florida College of Medicine in Gainesville (the “COM-GNV”) and the University of Florida College of Medicine in Jacksonville (the “COM-JAX”).

(b) “COM personnel” means any employee or appointee of the University of Florida (whether full-time, part-time or courtesy), including but not limited to Academic Personnel (AP), Technical, Executive, Administrative and Managerial Support (TEAMS), University Support Personnel System (USPS), and Other Personnel Services (OPS) employees, who has a COM appointment. Academic Personnel are defined in University of Florida Regulation 7.003 and include without limitation faculty members, residents, fellows, graduate assistants and post-doctoral associates.

(c) “Gifts” mean anything accepted by COM personnel, or by another person on behalf of the COM personnel, when equal or greater payment is not given within 90 days of receipt. Gifts include, without limitation, food or beverages, transportation, lodging, parking, membership dues, admission fees, flowers, personal services, preferential rates or terms on a debt, loans, goods or services, forgiveness of a debt, and the use of real property. Any prohibition against gifts does not extend to gifts from a relative.

(d) “Industry” means the pharmaceutical, medical device, and biotechnology industries and their representatives.

(e) “Industry-COM Conflict of Interest Committee” or “CIC” means the Industry Academic Relations Committee for COM personnel under the jurisdiction of the COM-GNV or the JAX Industry COM Conflict of Interest Committee for COM personnel under the jurisdiction of the COM-JAX. The compositions of the committees as well as the committee’s designees for any purposes set forth in this regulation are as set forth on the committees’ website at <http://coi.med.ufl.edu/contact-us/industry-academic-relations-committee/> and <https://www.hscj.ufl.edu/medicine/administrative-affairs/conflict-of-interest.asp>.

(f) “On-site” means facilities and grounds owned, operated or controlled by the University of Florida, the COM, or any affiliated patient-care facility.

(g) “Off-site” means facilities and grounds that do not fall under the definition of “On-site.”

(h) “Relative” means the spouse, domestic partner or fiancé of a COM personnel as well as the father, mother, son, daughter, brother, sister, uncle, aunt, first cousin, nephew, niece, grandfather, grandmother, great-grandfather, great-grandmother, grandchild, great-grandchild and the spouse, domestic partner, or fiancé of any of them, or any other natural person living in the same household as the COM personnel.

(i) “Speaker Bureaus” means any speaking engagement in which COM personnel are speaking on behalf of Industry as determined by the terms, conditions and intent of the agreement with the COM personnel when the following conditions apply: (i) the speech is not completely original to the COM personnel and all or part of the speech content is provided or dictated by or

on behalf of Industry-- or (ii) the content of the speech is subject to Industry approval.

(2) Introduction. COM personnel must pay particular attention to potential conflicts of interest in connection with Industry in order to protect the integrity of professional judgments and to preserve public trust in physicians, researchers, and academic medical institutions.

(3) Applicability of Policy. The COM Policy on Pharmaceutical, Medical Device, and Biotechnology Industry, Conflicts of Interest (“COM Industry Conflicts Policy”) applies to all COM personnel. The policy is supplemental to and does not supersede the University of Florida’s policy regarding the disclosure of outside activities, financial interests and conflict of interest, which is applicable to all University of Florida employees as set forth in University of Florida Regulation 1.011.

(4) General Statement of Policy

(a) The goal of the COM Industry Conflicts Policy is to increase transparency respecting Industry interactions and to eliminate or mitigate conflicts of interest created by these interactions. All interactions between COM personnel and Industry must be consistent with the policy.

(b) All COM personnel must become familiar with the COM Industry Conflicts Policy and are expected to understand and adhere to it.

(5) The COM Industry Conflicts Policy covers the following gifts and activities and, as in effect at any particular time, is more fully set forth at <http://coi.med.ufl.edu/contact-us/industry-academic-relations-committee/>. To the extent of any conflict or ambiguity between this or another University Regulation and the policy posted at the referenced Web site, this and other University Regulations shall govern. It shall not be a conflict, however, that the posted

policy merely imposes additional requirements and provides additional detail.

(a) COM personnel may not accept gifts from Industry regardless of the monetary value of the gift unless such a gift is specifically allowed under the COM Industry Conflicts Policy.

(b) COM personnel may not accept pharmaceutical samples and educational materials from Industry unless their acceptance is specifically allowed under the terms and conditions of the COM Industry Conflicts Policy.

(c) On-site access by Industry is restricted to areas open to the general public unless otherwise allowed under the COM Industry Conflicts Policy.

(d) Participation by COM Personnel in Continuing Medical Education (CME) and other educational activities is allowed only under the conditions set forth in the COM Industry Conflict Policy. The policy applies to both on-site and off-site educational activities and any training for or by Industry.

(e) COM Personnel participation in Industry-sponsored speakers bureaus is prohibited.

(f) Food/ Entertainment

1. COM personnel may not accept meals or any other gifts of food for themselves or others if sponsored or provided by Industry unless allowed by the COM Industry Conflicts Policy. The Policy applies to both onsite and offsite food or entertainment.

2. Industry requesting to support the educational mission of the COM may provide educational grants and gifts to the University. Such grants and gifts will be placed in an appropriate University or University of Florida Foundation, Inc. account and monitored and

distributed pursuant to applicable University and University of Florida Foundation, Inc. regulations, policies and procedures.

(g) No Ghostwriting. The professional presentations, books, articles, reports, or other materials, oral or written, of COM personnel must have appropriate authorship attribution.

(h) Scholarships/Fellowships. COM personnel may not accept scholarships or fellowships to support training initiatives from Industry. Scholarship and fellowship funds from Industry may be provided to the University of Florida or the University of Florida Foundation, Inc. as appropriate. Any such contribution or grant will be reviewed by the CIC. There shall be no quid pro quo associated with such funding.

(6) Disclosure and Notification.

(a) Outside activities and financial interests must be reported pursuant to the requirements of University of Florida Regulation 1.011. COM personnel who have no outside activities or financial interests to report are required to provide an annual attestation to that effect.

(b) COM personnel who present formal lectures to students or residents of the University of Florida must disclose at any presentation all outside activities, financial interests and relationships with Industry that relate directly or indirectly to the subject matter of the presentation.

Authority: BOG Regulation 1.001.

History: New.