

NOTICE OF PROPOSED REGULATION

Date: February 14, 2011

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. 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, 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, Sr. 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 Conflict of Interest Policy

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

(d) “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

_____ and _____.

(e) ‘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, grant-grandmother, grandchild, great-grandchild and the spouse, domestic partner, or fiancé of any of them, or any other natural person having the same legal residence as the COM personnel.

(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. This policy applies to all COM personnel. This 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 this 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 this policy.

(b) All COM personnel must become familiar with this policy and are expected to understand and adhere to it.

(5) Specific Activities

(a) Gifts. COM personnel may not accept gifts from Industry regardless of the monetary value of the gift unless such a gift is specifically allowed under this policy. A “gift” is 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.

(b) Pharmaceutical Samples and Educational Materials

1. Pharmaceutical Samples. Generally, COM personnel may not accept pharmaceutical samples unless those samples are forwarded to the pharmacy service identified by the applicable CIC. The pharmacy will distribute such samples through a voucher system. However, if a COM faculty physician believes the use of the voucher system rather than direct provision of samples to patients would jeopardize a vulnerable population of patients, or would otherwise adversely impact the appropriate and timely delivery of healthcare, the physician may request a waiver of this requirement from the entity identified by the applicable CIC for this purpose. A physician requesting a waiver must show a clear and convincing benefit and provide safeguards for the appropriate distribution and control of samples when the waiver is granted. Samples shall not be accepted for personal use by any COM personnel.

2. Teaching Aids/Books/Devices/Educational Materials. COM personnel are not permitted to accept books, instruments and other teaching aids from Industry. Industry may support the educational mission of the COM by providing educational grants or gifts of the above-listed items to the COM under the conditions stated in this paragraph. Grant or gift funds will be placed in an appropriate University of Florida or University of Florida Foundation, Inc. account and be monitored and distributed pursuant to applicable University and University of Florida Foundation, Inc. regulations, policies and procedures. Additionally, educational

materials may be donated by Industry to COM for use by COM personnel and students or for patients provided the donation of such materials is preapproved by the CIC and the materials are not branded by their supplier. Such materials may not be distributed directly to COM faculty, residents, staff and students or to patients by Industry. In special circumstances, COM personnel may request a waiver of this requirement from the CIC.

(c) On-Site Access by Industry.

1. On-site access by Industry is restricted to areas otherwise open to the public.

Access to patient-care areas, faculty offices, and other non-public areas may be permitted when Industry presence is necessary for educational purposes and then only by appointment and, when appropriate, with the prior consent of the patient, where applicable. On-site access to non-public areas by Industry must be under the constant supervision of a COM faculty member. These activities also are subject to the applicable policies of Shands HealthCare or other patient-care facility regarding such access.

2. On-site access by Industry at “vendor fairs” is permitted with the preapproval of the CIC.

(d) Continuing Medical Education (CME) and Other Educational Activities.

1. On-Site Educational Activities. COM personnel may engage in educational activities on-site in conjunction with Industry under the conditions set forth in this paragraph. CME courses must conform to ACCME standards and must be processed through and approved by the COM’s CME office. A complete description of the Standards of the ACCME to ensure independence in CME activities is available at:

http://www.accme.org/dir_docs/doc_upload/68b2902a-fb73-44d1-8725-

[80a1504e520c_uploaddocument.pdf](http://www.accme.org/dir_docs/doc_upload/68b2902a-fb73-44d1-8725-80a1504e520c_uploaddocument.pdf). Any non-CME educational activities that involve the

participation of Industry shall be conducted in accordance with this regulation and in such a manner as to insure that Industry participation is fully disclosed to all participants.

2. Off-Site Activities. COM personnel may participate in or attend off-site Industry-sponsored conferences and meetings or may attend conferences and meetings of tax-exempt organizations that are funded or sponsored by more than one entity which include Industry only if the conference or meeting conforms to the following conditions: (a) the activity is designed to promote evidence-based clinical and/or advance scientific research, and (b) the financial support of Industry is prominently disclosed. In addition, if the COM personnel is an attendee: (a) Industry may not pay attendee's travel and attendance expenses; and (b) attendees may not receive gifts or other compensation for attendance. COM personnel may participate in meals provided to all attendees as part of the general program. If the COM personnel is a compensated speaker at the activity, the following additional conditions apply: (a) all lecture content must be determined by the COM personnel and reflect a balanced assessment of the current science and treatment options, (b) the speaker must make clear that the views expressed are the views of the speaker and not the COM, (c) the compensation is reasonable and limited to reimbursement of reasonable travel expenses and a modest honorarium, (d) the speaker must take vacation time for the event; and (e) the activity is otherwise allowable under University of Florida Reg. 1.011.

3. On-Site Training conducted by or for Industry. Industry may provide on-site training to COM faculty, residents, staff and students with preapproval from the COM's CME office or the CIC. Such training shall be conducted in accordance with ACCME standards. Industry may also receive on-site training from COM personnel in the safe and proper use of medical devices and equipment. Training to be conducted in patient care areas must conform to Shands HealthCare policy or other applicable patient care facility policies. All required non-

CME training that involves the participation of Industry shall be pre-approved by the Chair of the applicable department and by the CIC.

(e) Speaker Bureaus. COM personnel participation in industry-sponsored speakers² bureaus is prohibited. A speakers bureau activity is any speaking engagement in which COM personnel are speaking on behalf of Industry as determined by the terms, conditions and intent of the agreement between the parties, and the speech is not completely original to the COM personnel, the speech is subject to Industry approval, the attendees are selected by Industry, or the attendees are provided a gift or stipend by Industry. The COM shall not sponsor and/or host any speakers bureau events. Speaking activities sponsored by Industry that are not expressly prohibited as speaker²s bureau activities shall be evaluated and approved by the CIC on a case-by-case basis.

(f) Food/ Entertainment

1. On-Site Food

a. Generally, COM personnel may not accept meals or any other gifts of food for themselves or others if sponsored or provided by Industry. 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.

b. Notwithstanding the foregoing paragraph, food supplied by Industry in conjunction with a CME event sponsored by the COM may be allowed provided any provision of food complies with ACCME guidelines.

2. Off-Site Food/Entertainment

a. COM personnel may not accept food for themselves or others sponsored or provided by Industry at off-site locations at non-CME events unless specifically allowed under this policy. COM personnel may not accept such food at CME events unless the event at which the food is to be served has been approved by the CME office. Industry funding may not be accepted for departmental meetings, retreats or social events. Meals or entertainment paid for by Industry for a small group of select individuals at regional or national meetings/conferences are not permitted.

b. COM personnel may attend educational events during regional and national meetings/conferences where food is provided by or sponsored by Industry provided such events adhere to ACCME standards.

(g) Travel to Meetings/Honoraria for Attendance. COM personnel are not permitted to accept travel funds or payment from Industry to attend a meeting or conference except in the following circumstances: (i) as reasonable reimbursement for travel to provide contractual services to Industry pursuant to an approved outside activity, (ii) to view capital equipment *in situ* if the equipment is being considered for purchase or to receive training in the use of the equipment as part of the COM personnel's University duties as long as Industry pays the monies for the travel to the University and the travel reimbursement to the COM personnel is paid pursuant to University travel policies; or (iii) to participate in meetings or otherwise travel pursuant to the terms and conditions of a sponsored research contract or grant to the University in which case the travel reimbursement to the COM personnel is paid pursuant to University travel policies. Travel for COM personnel attending professional meetings may be allowed under grants to the University that by their terms allow for the support for such travel. However, the decision to use gift funds for travel expenses will be made by the applicable department chair and

the dean who may consult with the CIC on the matter. A department chair's use of funds for his or her own travel must be approved by the dean in consultation with the CIC. Students and trainees may accept travel funds from scientific societies and charitable organizations, whether or not industry is the source of the funds, provided the society, organization, or department controls the selection of the recipient of the travel support.

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

(i) 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) Medical School Curriculum. The COM Curriculum Committee shall ensure that medical students at the University of Florida understand the importance of federal, state, and institutional conflict of interest laws, rules, policies and procedures. All University of Florida medical students shall receive specific instruction regarding this Conflict of Interest Policy.

Authority: BOG Regulation 1.001.

History: New _____.