

UNIVERSITY OF FLORIDA
COLLEGE OF MEDICINE - GAINESVILLE
CONFLICT OF INTEREST POLICY

College of Medicine Policy on Interactions with the Pharmaceutical, Medical Device¹, and Biotechnology Industries²

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

(a) “*COM*” means the University of Florida, College of Medicine in Gainesville.

(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 any Academic Personnel (AP), Technical, Executive, Administrative and Managerial Support (TEAMS), University Support Personnel System (USPS), and Other Personnel Services (OPS) employee, 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) “*IARC*” means the COM Industry Academic Relations Committee, which shall be composed of no less than twelve (12) members invited by the Senior Associate Dean for Clinical Affairs. The Senior Associate Dean for Clinical Affairs shall serve as the Chair of the

¹ The definition of “medical device” will follow the definition and any available guidance related thereto of the Federal Safe Medical Device Act of 1990, as amended, (21 CFR 821.1, <http://www.fda.gov.cdrh/comp/guidance/169.html>)

² Brennan, T. et al. Health Industry Practices that Create Conflicts of Interest. *JAMA*. 2006; 295: 429-433.

Committee. The director of the COM Conflict of Interest Program shall serve as staff to the Committee.

(2) **Introduction.** COM personnel must pay particular attention to potential conflicts of interest³ in connection with Industry in order to protect the integrity of professional judgments⁴ and to preserve public trust in physicians, researchers, and academic medical institutions. At the same time there are many legitimate, important and necessary interactions between COM personnel and Industry⁵. Therefore, the COM has established this policy to define the boundaries regarding acceptable interactions with Industry and to provide mechanisms to monitor these interactions.

(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 1.011⁶.

(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

³ See Thompson DF. Understanding financial conflicts of interest. *NEJM* 1993;329:573-6 (defining "conflict of interest, generally).

⁴ De Martino, B., Kumaran, D., Seymour, B., & Dolan, R. (2006). Frames, biases, and rational decision making in the human brain. *Science* 313, 684–687.

⁵ Lo B, Field MJ. Conflict of interest in medical research, education, and practice. Washington, DC: National Academies Press, 2009.

⁶ <http://www.generalcounsel.ufl.edu/downloads/COI.pdf>

expected to understand and adhere to it. The Conflict of Interest Program Office provides online and in-person policy education opportunities by appointment. COM personnel should consult with the Director, Conflict of Interest Program, College of Medicine, with questions or to obtain further guidance. COM personnel ultimately are individually accountable for their actions.

(5) **Specific Activities.**

(a) Gifts⁷. As provision of financial support or gifts, even in modest amounts⁸, can exert a subtle but measurable impact of recipients' behavior⁹, COM personnel may not accept gifts from Industry regardless of the monetary value of the gift¹⁰ 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, loan, goods or services, forgiveness of a debt, and the use of real property. Any prohibition against gifts does not extend to gifts from a relative¹¹.

⁷ Wazana A. Physicians and the Pharmaceutical Industry: Is a gift ever just a gift? *JAMA*. 2000; 283:373-80

⁸ Brennan TA, Rothman DJ, Blank L, et al. Health Industry practices that create conflicts of interest: A policy proposal for academic medical centers. *JAMA*. 2006; 295:429-433, See also Dana J, Loewenstein G.A. Social science perspective on gifts to physicians from industry. *JAMA*. 2003;290:252-5

⁹ Camerer, C., Loewenstein, G., & Prelec, D. (2005). Neuroeconomics: How neuroscience can inform economics. *Journal of Economic Literature*, 43(1), 9–64.

¹⁰ Katz, D., Caplan, A.L., & Merz, J.F. (2003). All gifts large and small: Toward an understanding of the ethics of pharmaceutical industry gift-giving. *American Journal of Bioethics*, 3(3), 39–46.

¹¹ "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.

(b) Pharmaceutical Samples and Educational Materials.

1. Pharmaceutical Samples¹². Generally, COM personnel may not accept pharmaceutical samples¹³. However, under certain, narrow circumstances, if a COM faculty physician believes lack of 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 University of Florida Physicians Clinical Safety Committee. 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 use¹⁴ by any COM personnel.

2. Teaching Aids/Books/Devices/Educational Materials/Equipment. COM personnel are generally not permitted to directly accept books, instruments, equipment, or teaching aids from Industry¹⁵. 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 or University of Florida Foundation account and monitored/distributed pursuant to University and/or University of Florida Foundation regulations, policies and procedures. Additionally, educational materials may be donated by Industry to COM for use by COM personnel and

¹² Kaiser Family Foundation. Prescription drug trends 2007. Kaiser Family Foundation; 2007.

¹³ Chren MM, Landefelde CS. Physician's behavior and their interactions with drug companies. *JAMA* 1994;271:684-9

¹⁴ Westfall JM, McCabe H, Nicholas RA. Personal use of drug samples by physicians and office staff. *JAMA*. 1997;278:141-143. Comments in *JAMA*. 1998;279:1698-99

¹⁵ Wofford JL, Ohl CA. Teaching appropriate interactions with pharmaceutical company representatives: The impact of an innovative workshop on student attitudes. *BMC Med Educ*. 2005 Feb 8;5(1):5.

students or for patients provided such materials are preapproved by the IARC and are not branded by the supplier of the materials. Such materials may not be distributed directly to COM faculty, residents¹⁶, staff and students or to patients by Industry. In special circumstances, COM personnel may request a waiver of this requirement from the IARC.

(c) On-Site Access by Industry.

1. On-site access by Industry is restricted to areas otherwise open to the public. All Industry representatives are required to register with the University of Florida's automated vendor registration system at one of several registration kiosks located on the University of Florida campus. Failure to register shall result in penalties up to and including denial of access. 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 policies of Shands HealthCare, as applicable, regarding such access.

2. On-site access by Industry at "vendor fairs" is permitted with the preapproval of the IARC. No gifts may be given by Industry in connection with such allowed access.

(d) Continuing Medical Education¹⁷ (CME) & Other Educational Activities.

1. On-Site Educational Activities. COM personnel may engage in educational

¹⁶ Schneider JA, Arora V, Kasza K, Van Harrison R, Humphrey H. Residents' Perceptions Over Time of Pharmaceutical Industry Interactions and Gifts and the Effect of an Educational Intervention. *Acad Med.* 2006 Jul;81(7):595-602

¹⁷ Steinbrook, R. "Commercial support and continuing medical education." *NEJM* 352(3):534-535. 2005

activities on-site in conjunction with Industry under the conditions set forth in this paragraph. CME courses must conform to ACCME standards¹⁸ and must be processed through and approved by the COM's CME office. 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 ensure that Industry-participation is fully disclosed.

2. Off-Site Events. COM personnel may participate in or attend Industry-sponsored conferences and meetings and/or conferences and meetings of tax-exempt organizations that are funded or sponsored by more than one entity, which may include Industry, provided: (a) the activity is designed to promote evidence-based clinical care and/or advance scientific research; (b) the financial support of Industry is prominently disclosed; (c) if the COM personnel is an attendee, Industry does not pay attendee's travel and attendance expenses; and (d) attendees do 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 participating as a compensated speaker: (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; and (c) compensation is reasonable and limited to reimbursement of reasonable travel expenses and a modest honorarium.

3. On-Site Training 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 IARC. Such training shall be conducted in accordance with ACCME standards. Industry may

¹⁸ http://www.accme.org/dir_docs/doc_upload/68b2902a-fb73-44d1-8725-80a1504e520c_uploaddocument.pdf

also receive on-site training from COM personnel in the safe and proper use of certain medical devices and/or equipment. Training to be conducted in patient care areas must conform to Shands HealthCare policy, as applicable. 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 IARC.

(e) Speakers' Bureaus. COM personnel participation in Industry-sponsored speakers' bureaus is prohibited¹⁹. A "speakers' bureau" activity is defined in this policy as any speaking engagement in which COM personnel are speaking on behalf of Industry, as determined by the terms, conditions, and intent of the written agreement between the parties, where the content of the talk is not completely original to the COM personnel; or the talk is subject to Industry approval; or the attendees of the event are selected by Industry or provided a gift or stipend to attend. Speaking activities that are not expressly prohibited by the foregoing shall be evaluated by the IARC on a case-by-case basis. The COM shall not sponsor and/or host any speakers' bureau activities.

(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

¹⁹ The Institute of Medicine has recommended against participation in such activities and the Council on Ethical and Judicial Affairs of the AMA has also recommended against such activities.

educational mission of the COM may provide educational grants or gifts. Grant and gifts will be placed in an appropriate University or University of Florida Foundation Account and monitored/distributed pursuant to University and/or University of Florida Foundation regulations, policies and procedures.

b. Notwithstanding the foregoing, 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 may accept travel funds from Industry in the following circumstances: (i) for legitimate reimbursement for travel to provide contractual services to Industry pursuant to an approved consulting activity or other approved outside activity (ii) to view capital equipment *in situ* if the equipment is being considered for purchase or for training in the use of equipment, in which cases travel should be

reimbursed through University policies; or (iii) to participate in meetings directly related to ongoing sponsored research in which case travel should be reimbursed through University policies. Grants to the institution may be used in part to support travel for COM personnel attending professional meetings; however, the decision to use gift funds for travel expenses will be made at the discretion of the applicable department chair, the dean, and, if necessary, in consultation with the IARC. A department chair's use of funds for his/her own travel should be approved by the dean in consultation with the IARC. Students and trainees may accept travel funds from scientific societies, whether or not industry is the source of the funds, provided the society and/or department controls the selection of the recipient of travel support.

(h) No Ghostwriting²⁰. The professional presentations, books, articles, reports, or other materials, oral or written, of COM personnel must have appropriate authorship attribution²¹.

(i) Scholarships/Fellowships. COM personnel may not accept scholarships or fellowships to support training initiatives directly from Industry²². Scholarship and fellowship funds may be provided to the University of Florida Foundation or the University, as appropriate. Any such contribution or grant will be reviewed by the IARC. There shall be no *quid pro quo* associated with such funding.

(j) Outside Employment/Consulting.

1. COM personnel are permitted to engage in outside employment, consulting, and

²⁰ Flanigan et al. "Prevalence of Articles with Honorary Authors and Ghost Authors in Peer-Reviewed Medical Journals." *JAMA* .1998. 280(3). 222-224.

²¹ Fugh-Berman, A. The Corporate Coauthor. *J Gen Intern Med*. 2005 June; 20(6): 546-548.

²² Brendan B. McCormick et al., "Effect of Restricting Contact Between Pharmaceutical Company Representatives and Internal Medicine Residents on Post-training Attitudes and Behavior," *JAMA: The Journal of the American Medical Association* 286, no. 16 (2001): 1994-1999.

other similar compensated activities in addition to their COM employment provided such activities do not conflict with the employee's duties and responsibilities to the COM and to the University of Florida. Outside consulting activities must be formalized in a written agreement between the parties and such written agreement must be submitted to the Conflict of Interest Program Office with sufficient time to review the agreement for adherence to University policies, procedures and rules. Payments for services must reflect Fair Market Value. Department chairs are responsible for evaluating Outside Activity requests for potential conflict of commitment and shall disapprove any such request upon a finding of conflict of commitment. Furthermore, such activities must be permissible under applicable state and federal law. A condition for approval of any such activities involving Industry is that the COM personnel must show such activities further the mission of the COM.

2. Outside employment, consulting activities, and financial interests of COM personnel may be disallowed if they result in conflicts with the employee's duties, responsibilities, and obligations to the COM as set forth in University of Florida regulations²³. It is the responsibility of the COM personnel to ensure that no consulting or employment agreement that he or she enters into violates any University of Florida regulations and policies as well as state and federal laws.

(k) Purchasing.

1. COM personnel engaged in University purchasing are subject to the provisions of the University of Florida's regulation and applicable state and federal law regarding the disclosure of outside activities, financial interests and conflict of interest. Moreover, formulary committees and committees overseeing purchases of medical devices shall exclude those who

²³ <http://www.generalcounsel.ufl.edu/downloads/COI.pdf>

have financial relationships with Industry from voting on applicable purchases. Expert clinicians may advise such committees provided all conflicts are disclosed.

2. An approved disclosure form must be attached to each applicable Requisition to Purchase from an enterprise in which a COM personnel has a material financial or managerial interest. If there is a requisition prepared to purchase from an enterprise in which a COM personnel has a material interest, the COM personnel with the interest cannot approve the requisition. If the purchase is allowed under state law, the approval of the COM personnel's supervisor will be required when an outside interest exists regardless of whether the proposed purchases fall under the sole source, emergency, or special purchasing categories.

(1) Disclosure and Notification.

1. COM personnel wishing to engage in activities or hold financial interests that are required to be reported under University of Florida Regulation 1.011 have an obligation to disclose and receive approval prior to engaging in these activities and to assure that such activities do not infringe upon their responsibilities and obligations to the COM and to the University of Florida. Each COM personnel is responsible for complying with the regulations and laws concerning outside activities and financial interests.

2. COM personnel engaging in outside activities must take reasonable precautions to ensure that the outside employer or other recipient of services understands that he or she is engaging in the activities as an individual and not on behalf of the COM or the University of Florida. COM personnel may not use the University's resources, including its name or addresses, without express written approval from an administrator designated by the University of Florida President to approve such use. A request for the use of University resources must be submitted pursuant to the University of Florida Regulation 1.011.

3. The disclosure of outside activities and financial interests are to be reported on the University of Florida's form²⁴ titled, **Disclosure of Outside Activities and Financial Interests** (University Form OAA-GA-L-267/Rev. 04/02) which is to be reviewed by the department chair or immediate supervisor and forwarded to the dean or director as necessary for authorization. This form should be completed and filed prior to such time as the outside activity or financial interest begins and at the beginning of each fiscal year. If a material change in the information presented occurs during the year, a new form must be submitted. All paperwork associated with continuing outside employment/activity must be renewed on a fiscal-year basis.

4. COM faculty who present formal lectures to students or residents of the University of Florida must disclose any and all outside activities, financial interests or personal relationships with Industry at each presentation.

5. All reports of financial interests and other outside activities at the University of Florida, including all reports of any significant financial interests, are open to the public under Florida law. Additionally, COM personnel are expected to take appropriate steps to personally disclose significant financial interests to patients to allow patients to make informed decisions respecting their medical care.

(6) **Annual Reporting.**

(a) Total compensation. Prior to the end of each academic year, COM personnel reporting outside activities and financial interests during the year shall report the total financial compensation received for such activities.

(b) Annual Attestation. COM faculty, residents and staff who have no outside activities or financial interests to report are required to provide an annual attestation to that

²⁴ <http://www.generalcounsel.ufl.edu/downloads/Appendices/appendixB1.pdf>

effect.

(c) **Penalties and Enforcement.** COM personnel who fail to abide by the provisions of the COM's Policy on Industry Conflicts of Interest & Industry/Academic Relations are subject to appropriate disciplinary action in accordance with University regulations. Examples of sanctions are: disallowance or limiting outside activities, changes in assignment, limitations on research activities, fines, reduction in pay, demotion, written reprimand, suspension without pay, and termination for cause. The employee may be required to turn over to the University all or part of the compensation from an unapproved outside activity.

(7) **Responsibilities of Department Chairs and other Supervisors.** COM directors, department chairs and immediate supervisors are responsible for reviewing disclosures and for ascertaining that a COM personnel's COM and University of Florida responsibilities are not being abrogated by the activity. They must review the disclosure and notify the COM personnel whether or not the activity may be conducted. If not, the reasons for not allowing the activity must be provided. If the activity is allowed with conditions, the administrator shall state the conditions under which the activity may be pursued. The University's Office of Research must authorize the activity if it involves waiving any rights to intellectual property.

(8) **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.