

**Name of Policy:** Interactions with the Pharmaceutical and Medical Device Industry at the University of Toledo Health Science Colleges and at the University Medical Center

**Policy Number(s):** 3364-81-04-027-00

**Approving Officer:** Provost and Executive Vice President for Health Affairs

**Responsible Agents:** Vice Provost, Health Science Campus

**Scope of Policy:** All Colleges Health Science Campus



**Most recent revision:** June 18, 2009

**Initial Effective date:** 08/01/07

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| <input type="checkbox"/> New policy proposal               | <input checked="" type="checkbox"/> Minor/technical revision of existing policy |
| <input type="checkbox"/> Major revision of existing policy | <input type="checkbox"/> Reaffirmation of existing policy                       |

(A) Policy statement

It is the University's moral obligation to impartially pursue the advancement, preservation and dissemination of knowledge in order to improve the human condition. The public that we serve expects independent, unbiased, and highly professional opinion and behavior in all of our endeavors as members of the faculty and administrative staff.

The University actively encourages interaction with both the public and private sectors as an important component of its research, education, and public service activities. This policy is intended to define the acceptable interactions of the University of Toledo (UT) Health Science Campus (HSC) Colleges with the Pharmaceutical and Medical Device Industry (PMDI) in order to foster collaboration and partnership where appropriate, and minimize real or apparent conflicts of interest on the part of the faculty, residents and students in carrying out the University's clinical, educational and research mission.

The provisions in this policy will apply to all educational sites, except for the Area Health Education Centers (AHEC) programs and private physician offices, and to all faculty, except volunteer faculty, who are encouraged, but not required to follow the provisions of this policy.

(B) Purpose of policy

This policy is established to provide an academic environment in the UT-HSC Colleges and the UT Medical Center (UTMC) that minimizes conflicts of interest and is conducive to evidence-based learning, the promotion of high quality ethical research, and excellence of patient care.

(C) Procedure

- (1) PMDI representatives are permitted to have only faculty-mentored interactions with students or residents. When PMDI representatives wish to have interactions with UT-HSC Colleges' students or residents, they must first make arrangements and schedule time with a member of the faculty to be present during this interaction.
- (2) Gifts to UT students, faculty and other employees by PMDI representatives and other vendors are prohibited at the UTMC, on the UT Campuses and at off campus educational and clinical sites. Included in the category of gifts are any items of value, such as textbooks, treatment handbooks, pens, or flash drives; and items of little or no monetary value that serve as free advertising or name-recognition reminders for the company, such as sticky notes, pads, calendars. Reprints of journal articles are not considered gifts if generally provided at no cost to the general public.

If industry wishes to provide support for educational materials for students, residents, or faculty for the purchase of handbooks or monographs, it must be done through an unrestricted educational grant or donation to a department, college, or the UT Foundation. The department or college will select the appropriate educational material and distribute it as deemed appropriate by the department or college. The sponsors of the grants that make the educational gift possible will be appropriately recognized and acknowledged at the time the gifts are distributed in accordance with state of Ohio ethics laws.

- (3) As long as the patient education and patient support information is generally available at no cost to the public, PMDI representatives and other vendors may provide such approved patient education and patient support information to the inpatient and outpatient nursing units, pharmacy, operating room and other relevant UTMC units, provided they have had UT review for accuracy and fairness. Branding with product name is not acceptable, unless for necessary patient support or education with that that particular product. Branding with the company name on educational material is acceptable as it acknowledges the educational contribution of that company. The industry representative may not give any such materials directly to the staff, but to the manager of the unit to use and distribute as determined appropriate by them to enhance education and facilitate patient care.
- (4) Meals (including snacks and drinks) and speakers at UTMC or HSC Colleges' grand rounds, conferences and other formal or informal meetings may be supported by industry only if the industry sponsors such activities through an unrestricted educational grant or similar support to be used at the discretion of the Office of Continuing Medical Education (CME), the Office of Continuing Nursing Education (CNE), the Office of Continuing Pharmacy Education (CPE), the College or the academic department. Additional provisions are that
  - The event is a CME, CNE or CPE approved or an officially sponsored departmental educational event; and

- There is no drug or device promotional association with the event.

Industry representatives must work through the CME, CNE or CPE office or the office of the academic department chair to make arrangements for sponsorship of events. The unrestricted grants may be used for speaker fees and other costs (including meals) related to the educational activities, at the discretion of the CME, CNE or CPE office or academic department. Industry support will be appropriately recognized and acknowledged during the educational event.

- (5) Evidence-based medicine (EBM) education and training for students and residents across the Health Science Campus will include didactic presentations and interactive training that address issues of conflict of interest, professionalism, and ethics as they relate to pharmaceutical and device promotion to physicians, other health professionals, and patients. This will include an emphasis on the practical relevance of EBM in the clinical setting. Details of the education programs will be developed by established curricular procedures.
- (6) Pharmaceutical and device industry representatives are permitted to visit UTMC, provided they register and conduct themselves in accordance with UTMC policy number 3364-133-44, "Pharmaceutical Representatives."
- (7) Provision and use of drug samples will continue to be governed by UTMC Ambulatory Policy 3364-101-06-03 Guidelines for Receiving, Dispensing, and Disposal of Drug Samples.
- (8) Industry support of symposia, conferences and other events designed for post-graduate health professionals in Northwest Ohio and beyond, which are sponsored totally or in part by the UT Office of CME, CNE, or CPE will be encouraged as long as such events are in full compliance with Ohio ethics laws. Sponsor support will be officially acknowledged where appropriate. Booths, tables and displays to provide product information and discussion with industry representatives will continue to be permitted. However, neither gifts of value nor token reminders, such as pens or pads will be permitted at these display areas. CME activities are governed by policies A-10-12-00001 to 00006-0206.

It is intended that this mechanism will continue to offer opportunities for pharmaceutical and medical device representatives and other vendors to present and provide information about their products.

The CME, CNE, and CPE offices will monitor adherence to the spirit and content of this policy at these events.

- (9) Access to patient care areas by pharmaceutical or device manufacturer representatives will be permitted only when the representatives are appropriately credentialed by UTMC and may take place only by appointment or invitation of an attending physician or other UT faculty member. The representatives will not be allowed to be present during any patient care interaction, unless there has been prior disclosure to and consent by the

patient, and then only to provide or receive in-service training or assistance on devices and equipment.

Payments to any UT Provider of care or other UT employee from the PMDI or its representatives in exchange for this access and interaction are not permitted.

- (10) Faculty, students and trainees are advised to carefully consider the professional implications of accepting payment for attendance at non-CME, non-CNE, or non-CPE accredited industry-sponsored off-campus events or accepting personal gifts, including meals, from industry at such events as state employees or students in training.
- (11) Faculty may participate in industry-sponsored speakers' bureaus in compliance with Ohio law (faculty who hold administrative positions may have additional restrictions), however they are required to
  - (a) Provide scientifically balanced presentations,
  - (b) Disclose to the University the nature and extent of such activities, and
  - (c) Utilize personal or vacation time for such activities, or work time if approved.
- (12) Promotion or marketing of UT or UTMC programs to the community should not be supported by the PMDI, unless through an unrestricted grant or gift to the college of the UT Foundation.
- (13) Faculty, students, and trainees are prohibited from directly accepting travel funds from industry.
- (14) PMDI representatives will be required to take a two-hour UT-sponsored education class or comparable on-line education on relations between industry and UT students and residents. All PMDI representatives are required to take the course within 12 months of their first registering as an industry representative with the UTMC Pharmacy or Purchasing Office or starting any activity at the UTMC.
- (15) Failure of industry representatives to adhere to this requirement may result in sanctions, including rescinding of the privilege of visiting the UT-HSC campus.
- (16) The sponsoring of athletic events, programs and functions by a PMDI in exchange for naming rights or exclusive marketing rights, or the support of financial aspects of an athletic event, program or function by a PMDI are expressly excluded from this policy. Such support must comply with all other applicable law and University policy.

*Many of the provisions in this policy were taken directly or modified from various documents from the Association of American Medical Colleges, including their "Report of the AAMC Task Force on Industry Funding of Medical Education to the AAMC Executive Council," June 2008.*

Approved by: Jeffrey Gold, M.D. _____ Name Provost and Executive Vice-President for Health Affairs Title <u>June 18, 2009</u> Date  <i>Review/Revision Completed by:</i>	<b>Policies Superseded by This Policy:</b> <i>None</i>  <b>Initial effective date:</b> 08/01/07  <b>Review/Revision Date:</b> June 18, 2009  <b>Next review date:</b> 08/01/10
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