


<b>Name of Policy:</b> <a href="#"><u>College of Medicine and Life Sciences: Interactions with the Pharmaceutical and Medical Device Industry and other Vendors at the University of Toledo Health Science Colleges and at The University Medical Center</u></a>		 <p><b>Effective date:</b> November 29, 2021</p> <p><b>Original effective date:</b> August 1, 2007</p>	
<b>Policy Number:</b> 3364-81-04-027-00			
<b>Approving Officer:</b> Executive Vice President for Clinical Affairs, Dean College of Medicine and Life Sciences			
<b>Responsible Agent:</b> Executive Vice President for Clinical Affairs			
<b>Scope:</b> All Health Science Colleges			
<input type="checkbox"/>	New policy proposal	<input type="checkbox"/>	Minor/technical revision of existing policy
<input type="checkbox"/>	Major revision of existing policy	<input checked="" 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 Colleges with the Pharmaceutical and Medical Device Industry (PMDI) and other vendors 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 Health Science 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. This policy is not intended to impede scientific research or transfer of technical knowledge or education.

(C) Scope

This policy pertains to all colleges on the health science campus concerning the Pharmaceutical and Medical Device Industry (PMDI) and other vendors.

(D) Procedure

- (1) A Pharmaceutical and Medical Device Industry (“PMDI”) Representative is defined as a person hired or paid any value by the PMDI to represent the interests of a pharmaceutical or device corporation or person. Faculty with consulting arrangements with a PMDI will not be considered PMDI Representatives under this policy unless such faculty member takes any action on behalf of the PMDI with which the faculty member has a consulting arrangement, either directly or indirectly, that involves any University student, resident or other faculty member.
- (2) PMDI Representatives or other vendors are permitted to have only faculty-mentored interactions with students or residents. When PMDI Representatives or other vendors wish to have interactions with UT Health Science Colleges’ students or residents, they must first make arrangements and schedule time with a member of the faculty to be present during this interaction. Faculty members who schedule time with PMDI Representatives for student or resident interactions must be available and attend the entire PMDI Representative visit with the students or residents.
- (3) Gifts to UT students, faculty and other employees by PMDI Representatives and other vendors are prohibited at UTMC, on the UT Campuses and at off campus 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 or calendars. Reprints of journal articles are not considered gifts if generally provided at no cost to the general public.
- (4) If PMDI Representatives or other vendors wish 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.
- (5) 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 no generic version of the product is approved for use by the Food and Drug Administration. Branding with the company name on educational material is acceptable as it acknowledges


the educational contribution of that company. The PMDI Representative or other vendor 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.

- (6) Meals (including snacks and drinks) and speakers at UTMC or Health Science Colleges' grand rounds, conferences and other formal or informal meetings may be supported by the PMDI or other vendors only if such activities are sponsored 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 Academy for Professional Development (APD), the College or the academic department. Additional requirements are that:
  - (a) The event is a CME, CNE or CPE approved or an officially sponsored departmental educational event; and
  - (b) There is no drug, device, other product or service promotion associated with the event.
  - (c) Any PMDI or other vendor 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.
- (7) Evidence-based medicine (EBM) education and training for students and residents across the Health Science Colleges 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.
- (8) PMDI Representatives are permitted to visit UTMC, provided they register and conduct themselves in accordance with this policy and UTMC policy number 3364-133-44, "Pharmaceutical Representatives."
- (9) 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."
- (10) 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, APD 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 separate UT Policies.
- (11) 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.
  - (12) The CME, CNE, APD and CPE offices will monitor adherence to the spirit and content of this policy at these events.
  - (13) Access to patient care areas by PMDI Representatives or other vendors 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 medical devices and equipment.
  - (14) Payments to any UT Provider of care or other UT employee from the PMDI or other commercial vendors or its representatives in exchange for this access and interaction are strictly prohibited.
  - (15) 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. State employees may not accept such payments or personal gifts if the payment or gift is prohibited by the Ohio ethics law.
  - (16) 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.
  - (17) Promotion or marketing of UT or UTMC programs to the community should not be supported by the PMDI or other commercial entities, unless through an unrestricted grant or gift to the college or the UT Foundation.

- (18) Faculty, students, and trainees are prohibited from directly accepting travel or travel funds from industry unless the travel is for a faculty member under a University approved consulting arrangement and is separate from University business.
- (19) PMDI Representatives and other vendors will be required to take a two-hour UT-sponsored education class or comparable on-line education on relations between industry and university students and residents. All PMDI Representatives and other vendors 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 UTMC.
- (20) Failure of industry representatives to adhere to this requirement may result in sanctions, including rescinding of the privilege of visiting the UT-HSC campus or interacting with UT and its faculty, residents, and students.
- (21) The sponsoring of athletic events, programs and functions by a PMDI Representative or other vendors 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 Representative or other vendor is 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.*

<p>Approved by:</p>  <p>_____  Christopher Cooper, M.D.  Executive VP for Clinical Affairs and Dean,  College of Medicine and Life Sciences</p> <p><u>November 29, 2021</u>  Date</p> <p><i>Review/Revision Completed by:</i></p> <p><i>Dean, College of Nursing</i>  <i>Dean, College of Pharmacy</i>  <i>Associate Vice President and Senior</i>  <i>Legal Counsel</i>  <i>Dean, College of Education, Health</i>  <i>Science &amp; Human Service</i>  SLT</p>	<p><b>Policies Superseded by This Policy:</b></p> <ul style="list-style-type: none"> <li>• <i>None</i></li> </ul> <p>Initial effective date: 08/01/07</p> <p>Review/Revision Date:  05/01/09  08/12/10  11/01/13  08/15/18  11/29/21</p> <p><b>Next review date: November 29, 2024</b></p>
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