



DES MOINES UNIVERSITY

POLICIES AND PROCEDURES

Department: Des Moines University - Osteopathic Medical Center
Subject: Conflict of Interest Policy – Pharmaceutical and Industry Representatives
Date Issued: April 14, 2009
Date Revised: April 20, 2010
Approved By: Karen McLean, Ph.D., Provost
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I. PURPOSE

This policy establishes guidelines for interactions between Industry representatives and students as well as healthcare staff and faculty of Des Moines University (DMU).

II. DEVELOPMENT OF THIS POLICY

The Association of American Medical Colleges (AAMC), the Prescription Project, the American Medical Student Association (AMSA) and various policy leaders have urged all academic medical centers to “accelerate their adoption of policies that better manage, and when necessary, prohibit, academic-industry interactions that can inherently create conflicts of interest and undermine standards of professionalism”¹ Importantly, according to the AAMC, it is the obligation of students...and faculty in the health professions “to manage all conflicts of interest, *real and perceived* through effective self-regulation”. Therefore, the faculty, staff, students and administration of Des Moines University have adopted the following policies to govern and guide their interactions with pharmaceutical and biomedical device company representatives.

III. SCOPE

This policy applies to all DMU students, applicable staff, part and full-time faculty members employed by DMU.

IV. DEFINITIONS

Academic Medical Center (AMC) – refers to all DMU campus buildings.

Conflicts of Interest (COI) – Any situation in which an individual is in a position to exploit his/her professional or official capacity in some way for personal benefit.

Continuing Medical Education (CME) – any medical education program which complies with the Accreditation Council for Continuing Medical Education (ACCME) Standards for Commercial Support of Educational Programs, AOA Council for Continuing Medical Education (CCME) or other similarly rigorous, applicable standards required by other health professions.

Industry – all pharmaceutical manufacturers and biotechnology, medical device and clinic supply entities.

Industry representatives – all sales, marketing and other product-oriented personnel soliciting the use of any drug, drug-related products or biomedical devices.

Promotional items – any non-educational or practice-related items of minimal value (such as pens, notepads, and similar “reminder” items with company or product logos).

University Clinic – DMU Clinic

University Campus – composed of AMC and University Clinic.

V. STATEMENT

It is the policy of DMU that interactions with Industry should be conducted to avoid or minimize real or perceived COI. This policy has been created to establish more explicit standards between DMU and Industry and is divided into sections as noted below: The major domains of COI addressed are:

- A. Interactions with Industry Representatives
- B. Consulting relationships (excluding scientific research and speaking)
- C. Industry-sponsored speaking relationships
- D. Disclosure of conflicts of interest
- E. Provision of pharmaceutical samples and biomedical devices
- F. Site Access by industry representatives – refer to A. above
- G. Continuing medical education
- H. Compensation for Travel or Attendance at Off-site Lectures and Meetings
- I. Provision of scholarships and Other Educational Funds for Students
- J. Training of students, staff and faculty regarding potential conflicts of interest with industry
- K. Compliance and oversight
- L. Implementation and Review

A. Interactions with Industry Representatives in the Academic Medical Center and the University Clinic

1. **Academic Medical Center Policy** – DMU students may have interactions with industry representatives in the AMC provided:

- a) The interaction has been requested in writing and approved as a curricular educational and/or a *club –sponsored* event by the Program Director or Dean of the pertinent college. Examples of these events include:
 - i) casting or taping seminars
 - ii) labs involving physical therapy modalities
 - iii) suturing exercises
 - iv) surgical skills labs
 - v) similar *club-sponsored* educational events
- b) These events must be actively mentored by DMU faculty
- c) *Club-sponsored* educational events must also be approved by the faculty advisor and the Office of Student Services.
- d) Pharmaceutical representatives must strictly comply with the latest PhRMA Code on Interactions with Healthcare Professionals
- e) Non-pharmaceutical representatives are encouraged to comply with the spirit of the above Code
- f) Promotional items and meals are prohibited
- g) The Club, Events and Organizations (CEO) Handbook's guidelines developed by the Office of Student Services will be consonant with this policy.

2. University Clinic Policy

- a) Gifts to individuals – Students, staff or clinicians may not accept any personal gift from industry or industry representatives even if the gift is of nominal monetary value (zero dollar amount). This policy encompasses gifts from equipment and service providers, as well as pharmaceutical and biomedical device providers.
- b) Provision of Meals – With the exception of CME as defined in Section IV, industry-supplied food and meals are considered personal gifts and will not be permitted or accepted within the University Clinic.
- c) Site Access by Industry Representatives – Industry representatives are permitted provided:
 - i) they have a standing invitation to visit the University Clinic
 - ii) they register at the 1st floor atrium security desk at the time of their appointment

- iii) they are aware that registration acknowledges that the representative has read and understands this policy
- iv) providers may or may not elect to visit with an industry representative
- v) all meetings must be restricted to non-patient care areas. Involvement of students and trainees in such individual meetings should occur only for educational purposes and only under the supervision of a faculty member.
- d) Educational Conferences – Industry-sponsored lectures are permitted provided:
 - i) it is designed to promote evidence-based clinical care
 - ii) it is under the supervision of a clinical faculty member
 - iii) speaker discloses any financial support or conflict of interest
 - iv) no industry-sponsored meals are provided.(see A.2.b)
- e) Promotional Items – Promotional items are not permitted in clinical practice areas or at educational conferences for students, staff and clinicians.

B. Consulting Relationships (excluding scientific research and speaking)

1. Consulting relationships with Industry are permitted under the following conditions:
 - a) All consulting relationships with Industry must be accompanied by a formal written contract that outlines specific deliverables, tasks, and responsibilities;
 - b) Compensation must be commensurate with the tasks performed considering the faculty member’s specialty, expertise and reputation.
 - c) It shall comply with DMU’s Disclosure of Industry Relationships and Secondary Employment Policy and the appropriate form shall be completed and forwarded along with a copy of the final contract to the department chair and Dean with a copy to the Provost.

C. Industry-sponsored speaking relationships

With the exception of settings in which academic investigators are presenting results of their industry-sponsored studies to peers and there is opportunity for critical exchange, DMU strongly discourages participation by its faculty and staff in industry-sponsored speakers' bureaus.

If faculty and staff choose to participate in industry-sponsored, FDA-regulated programs, they must meet the following conditions:

1. DMU requires full transparency and disclosure by faculty and staff when participating in such programs;
2. Any payments made to academic personnel must be at fair market value;
3. Faculty and staff may not permit industry representatives to provide, modify, veto or otherwise manipulate any content of the presentation; and
4. It shall comply with DMU's Disclosure of Industry Relationships and Secondary Employment Policy and the appropriate form shall be completed and forwarded to the department chair and Dean with a copy to the Provost.
5. Speaking relations with company or company event planners are subject to review and approval of the participant's Department Chair and Dean.

D. Disclosure of Conflicts of Interest

1. All DMU faculty, deans, and chairs shall disclose relationships with Industry by completing and forwarding the Disclosure of Industry Relationships and Secondary Employment Form prior to employment and annually thereafter. In addition, they will update their disclosures immediately upon entering a new or revised financial relationship.
2. All DMU faculty members when involved with the following relationships shall comply accordingly:
 - a. speaking, speaker's bureau - V. Section C.
 - b. consulting, consultant's bureau – V. Section B.
 - c. continuing education – all DMU speakers and planners shall disclose relationships with Industry pursuant to the Disclosure of Industry Relationships and Secondary Employment Policy, and the attached form shall be completed and forwarded to the Office of Community Relations. All DMU planners must comply with V. Section G.

In addition, DMU requires all teaching and lecturing faculty to disclose to students all relevant financial relationships that they have with any commercial interest. Such disclosure may occur as part of a slide presentation or as a declaration in the course syllabus.

3. All trustees, directors, administrators and other employees who serve in a management or supervisory capacity shall complete and forward the Conflict of Interest Disclosure Statement to the Chairperson of the Board.

E. Provision of pharmaceutical and biomedical devices

1. Provision of drug samples will be governed by the Industry/ Pharmaceutical Samples policy.
2. The practice of accepting free pharmaceutical samples has been shown to interfere with one's prescribing practices since industry representatives often provide the newest and most costly drugs. Therefore, pharmaceutical industry samples will be accepted in the DMU clinic only if *both* of the following *two* conditions are met:
 - a. Industry representatives interview with the DMU Pharmaceutical Review Committee to present the research evidence supporting the particular drug. The Pharmaceutical Review Committee after hearing the presentation determines there is evidence to support the use of the drug in the DMU Clinic; *and*
 - b. The Pharmaceutical Review Committee has determined there is no generic alternative to the drug.
3. The approved pharmaceuticals will only be given to patients that qualify under DMU Clinic's Financial Assistance Program.
4. DMU will track the dispensing of approved pharmaceuticals to DMU Clinic patients that qualify for the Clinic's Financial Assistance Program for 12 months following implementation of this policy.
5. The foregoing was placed into effect on May 11, 2010.
6. Faculty clinicians will educate staff and trainees about and inform patients of affordable options for obtaining medicines. Examples are pharmaceutical assistance programs, vouchers, and large retail chains with low-cost medicines and generics.
7. Faculty, staff and students may not accept free drug samples, medical devices or other supplies for personal use from industry or industry representatives.

F. Site Access by Industry Representatives – please refer to A.2.c

G. Continuing Medical Education

Industry support of continuing medical education (CME) can provide benefit to patients by ensuring that the most current, evidence-based medical information is provided to healthcare practitioners. In order to ensure that the potential for bias is minimized, all CME events hosted or sponsored by DMU, whether on or off campus, must comply with the Accreditation Council for Continuing Medical Education (ACCME) Standards for Commercial Support of Educational Programs, AOA Council for Continuing Medical Education (CCME) or other similarly rigorous, applicable standards required by other health professions. The Standards may be found at www.accme.org and http://www.do-online.org/pdf/cme_accredreqs.pdf respectively.

The Office of the Provost will serve as the university's central CME office through which all requests for industry support and receipt of funds for CME activity are coordinated and overseen.

H. Compensation for Travel or Attendance at Off-site Lectures and Meetings

1. DMU faculty, staff or students may not directly accept travel funds or reimbursement from Industry other than for legitimate contractual services. The employee shall complete and forward the Disclosure of Industry Relationships and Secondary Employment Form to their supervisor and Dean.
2. Each faculty and staff shall carefully evaluate their own participation in off-site meetings or conferences that are fully or partially sponsored or funded by Industry, because of the high potential for perceived or real COI.

I. Provisions of Scholarships and Other Educational Funds for Students

All scholarships and other educational funds from Industry shall be reported to the Vice-President for Development and monitored by the Accounting Department. The selection of recipients will be coordinated between the Office of Enrollment Management, Deans of each college when relevant and the Vice-President for Student Services in accordance with DMU's Scholarship policy. There shall be no involvement by the donor industry. There must be no quid pro quo for the acceptance of funds.

J. Training of students, staff and faculty regarding potential conflict of interest in interactions with industry. “Shielding students from all marketing activity will not prepare them for coping with the barrage of marketing they will face when they complete training and enter practice.”¹ Therefore, DMU and its three colleges, CPMS, CHS and COM, have developed an *interdisciplinary* instructional program that will help students understand the conflicts that may arise between industry representatives and health care professionals and how to develop and sustain productive and ethical relationships.^{2,3} The educational programs includes evidence-based medical education, literature search strategies and critical appraisal of the healthcare literature. This educational program will be the responsibility of the Office of the Provost who will monitor the evolutionary process.

K. Compliance and Oversight

1. Academic Medical Center

- a) Interactions with industry representatives as noted in V.A.1 will be under the oversight and compliance of the Program Director and/or Dean of the respective college.
- b) All remaining *club-sponsored* events – Vice-President for Student Services

2. University Clinic – Clinic Administrator

L. Implementation and Review

- 1. All DMU faculty, healthcare staff and students are expected to adhere to the content and spirit of this policy.
- 2. The Provost and Clinic Administrator will be responsible for implementation, interpretation, review and recommendations for policy improvement.
- 3. This policy will be reviewed at 6 and 12 months after inception to assure that unintended consequences be corrected.

¹ Association of American Medical Colleges, Report of the Task Force on Industry Funding of Medical Education to the AAMC Executive Council. Washington, D.C: 2008.

² Coleman DL, Kazdin AE, Miller LA et al. Guidelines for interactions between clinical faculty and the pharmaceutical industry: One medical school's approach. Acad Med 2006; 81:154-160.

³ Sierles FS, Brodkey AC, Clearly LM et al. Medical students' exposure to and attitudes about drug company interactions: A national survey. JAMA. 2005;294:1034-1042.