

TUFTS UNIVERSITY SCHOOL OF MEDICINE

2010 Revised Policy on Industry Conflicts of Interest

EXECUTIVE SUMMARY

Tufts University School of Medicine (TUSM), in an effort to recognize the potential effects of physician-industry and researcher-industry relationships, and to educate its students, hereby adopts the following policy:

- This policy applies to all faculty and administrators at TUSM and in TUSM-affiliated institutions (“TUSM faculty”) and all TUSM students.
- TUSM faculty and students shall not accept or use personal gifts and hospitality from representatives of industry regardless of the nature or value of the gift, except as noted herein.
- TUSM faculty and students shall not accept industry-funded meals except those in conjunction with CME activities that comply with the Accreditation Council on Continuing Medical Education (“ACCME”) standards for commercial support.
- TUSM faculty engaged by industry to provide consulting services must do so pursuant to a consulting contract that identifies specific tasks and deliverables and contains payment provisions commensurate to the tasks.
- Industry sales representatives are not permitted to interact with TUSM students except under the direct supervision of TUSM faculty in a structured learning environment.
- All CME events hosted at, or sponsored by, TUSM must comply with the ACCME Standards for Commercial Support of Educational Programs; for all off-campus, non-TUSM continuing education events, TUSM faculty must be aware of industry influence and must carefully evaluate whether to attend or participate on the basis of the criteria set forth in this policy.
- TUSM faculty participation in ghostwriting and industry-sponsored speaking engagements where the content and materials are controlled by the company is prohibited.
- TUSM faculty involved in research must comply with the Conflict of Interest policies set forth by the Tufts University Office of Research Administration or the institution sponsoring the research.
- TUSM faculty and guest lecturers involved in teaching TUSM students must disclose relationships with industry that relate to the content of their course or lecture or clinical teaching.
- TUSM faculty and administrators must report their relationships with Industry on an annual basis.

- All TUSM faculty, staff and students shall be notified of this policy.
- The Effective Date of this Revised Policy is April 5, 2010.
- An Industry Conflicts of Interest Advisory Committee has been established.

TUFTS UNIVERSITY SCHOOL OF MEDICINE

2010 Revised Policy on Industry Conflicts of Interest

A. Introduction

Medicine today often requires the dynamic interaction between the clinician/scientist and the pharmaceutical and medical device industries. This policy is intended to identify, clarify and avoid conflicts of interest between industry and TUSM faculty, administrators and students.

To this end, TUSM adopts the following policy:

B. Scope of Policy: Definition

(a) This policy applies to all TUSM faculty and administrators (hereafter called "TUSM faculty") in their activities at TUSM and TUSM-affiliated institutions and all TUSM students.

(b) While this policy addresses many aspects of Industry relationships, it supplements and does not supersede any existing Conflict of Interest policies of Tufts University or other institutions where TUSM faculty hold appointments. For purposes of this policy, "industry" is defined as all pharmaceutical manufacturers, biotechnology companies, medical device¹ and hospital equipment suppliers and their sales and marketing representatives.

(c) This policy applies to TUSM faculty and student interactions with all sales, marketing, or other product-oriented personnel of industry, specifically those individuals whose purpose is to provide information to clinicians about company products, whether or not such personnel are classified in their company in a "sales" or "marketing" capacity.

C. Statement of Policy

¹ The definition of "medical devices" as used here follows the definition and guidance provided by the Federal Safe Medical Device Act of 1990, as amended (21 CFR 821.1, www.fda.gov/cdrhlcomplguidance1169.html).

It is the policy of TUSM that education, clinical and research activities must be free from influence created by improper financial relationships with, or gifts provided by, representatives of industry. TUSM faculty and students are prohibited from participating in any commercial inducements (gifts, subsidies or hospitality) of any size or nature. The following specific limitations are set forth for purposes of guidance only. For other circumstances, TUSM faculty should consult in advance with their deans, department chairs or TUSM's Dean and Vice Deans to obtain further guidance and clarification. Charitable gifts provided by industry in connection with fundraising done by or on behalf of TUSM are not covered by this Policy.

D. *Specific Activities*

1. Gifts

TUSM faculty and students shall not accept or use personal gifts from representatives of industry regardless of the nature or value of the gift. The following items are considered gifts and are not permitted:

- (a) Free items of any nature or description, including, e.g., pens, notepads, totes, pharmaceutical samples for personal use.
- (b) Payment to attend meetings, lectures and conferences
- (c) Payment for participation in online CME activities.
- (d) TUSM faculty and students may not accept hospitality (e.g., complimentary tickets to sporting or other events) funded by industry, whether on or off-campus, except as set forth below.
- (e) Industry choosing to make charitable contributions to TUSM may contact the Development Office or any other charitable foundation legally organized to support TUSM. All such charitable contributions are subject to applicable policies maintained by TUSM.

2. Meals

Industry-funded meals or refreshments provided by sales or marketing representatives are prohibited at TUSM except those in conjunction with Continuing Medical Education that comply with the standards of the Accreditation Council of Continuing Medical Education ("ACCME") with regard to content validation and means. See subsection 6 below. TUSM will not hold any industry-sponsored talks or lunches that do not meet ACCME criteria.

3. Industry-Sponsored Speaking/Ghostwriting.

- (a) Industry-Sponsored Speaking and Lectures

Consistent with the *FDA Guidance for Industry-Supported Scientific and Educational Activities, (1997)*, speaking engagements that convey information

about a Company's products or their drug classes that are sponsored and controlled by a Company are promotional activities. TUSM prohibits participation in promotional activities.

A promotional activity, whether or not compensated, is characterized by the following:

- 1) The speaker appears to act as a Company's agent or spokesperson for the purpose of disseminating Company or product information; and
- 2) The Company controls the content of the presentation, which may include creating or having final approval over the slides or presentation materials or setting limits on the scope of discussion.

(b) Ghostwriting

TUSM prohibits acceptance of services of a ghostwriter provided by a Company. Ghostwriting occurs when (1) a representative of a Company or its agent makes a contribution to an article or other published material in a manner consistent with the International Committee of Medical Journal Editors (ICMJE) criteria for authorship or contributorship; (2) the contribution exerts influence or control over the content of the article; and (3) the contribution, including its relationship to a Company, is not disclosed.

ICMJE criteria require that all authors and contributors must be disclosed. Determination of authorship under ICMJE criteria is based on:

- 1) Substantial contributions to the conception and design, acquisition of data, or analysis and interpretation of data;
- 2) Drafting the article or revising it critically for important intellectual content; and
- 3) Providing final approval of the version to be published.

Contributors are those who have provided assistance, such as technical help or writing assistance.

4. Consulting Relationships

TUSM recognizes the value of consulting relationships and its duty to make available the knowledge, training and intellectual achievements of TUSM faculty to government, business and other organizations. TUSM also recognizes the potential value of these activities to TUSM and TUSM faculty. Nevertheless, consulting arrangements that offer TUSM faculty a guaranteed compensation without specific, associated duties (such as participating on scientific advisory boards that do not meet regularly or do not have specific, assigned tasks) are considered "gifts" and are thus prohibited. In order to avoid an appearance of impropriety or gifts disguised as consulting arrangements, TUSM faculty engaged by industry to provide consulting services must do so pursuant to a consulting

contract that identifies specific tasks and deliverables and contains payment provisions that are consistent with the assigned tasks. Industry-funded travel pursuant to a Consulting Contract is permitted.

5. Site Access and Complimentary Drug Samples/Devices

- (a) Industry (including pharmaceutical and medical device) sales representatives are not permitted in any TUSM area where patient care might occur except to provide training and guidance on the essential uses of devices and equipment, and only by appointment.

Industry (including pharmaceutical and medical device) sales representatives are not permitted to interact with TUSM students except under the direct supervision of TUSM faculty in a structured learning environment. Educational and administrative offices may not provide industry representatives with email addresses or mail distribution lists. Any involvement of students and trainees in meetings with industry representatives may only occur for educational purposes and only under the supervision of a TUSM faculty member.

- (b) On-campus vendor fairs intended to showcase drugs or medical devices are permitted only with the prior approval of the Office of the Dean or Vice Dean. Such events must comply with the "gifts" provision of Sections 1 of this policy. Vendors may not be permitted to distribute free samples, meals, raffle tickets or other gifts to attendees.
- (c) Complimentary drug samples and medical devices are prohibited at TUSM.
- (d) On-campus demonstrations of research equipment prior to purchase are permitted.
- (e) In the event that purchasing of drugs or devices for patient care on or behalf of TUSM is sought, TUSM must first create a Pharmaceutical and Device Procurement Committee that consists of members with no financial relationship with manufacturers including consulting contracts, grants or any other arrangement resulting in gifts or compensation to members.

6. Continuing Medical Education

(a) *TUSM-Sponsored Events*

1) All continuing education events held at TUSM or sponsored by TUSM will fully comply with the standards set forth by the Accreditation Council on Continuing Medical Education ("ACCME"), whether or not Continuing Medical Education ("CME") credit is awarded.

2) Industry support for CME must be handled by the Office of Continuing Education to address the suitability of the industry support, account for it and distribute funds for CME-certified activities and programs. The Office of Continuing Education may designate CME

funds to go directly to joint sponsors. Full documentation, including a signed commercial support agreement, is required.

(b) Non-TUSM-Sponsored (Off-Campus) Events

Industry support of CME, in whole or in part, can benefit the health of the public by ensuring that current, evidence-based medical information is provided to healthcare practitioners. In order to ensure that potential for bias is minimized and that CME programs are not a guise for marketing, all CME events in which TUSM faculty or Students attend or participate must conform to the following guidelines:

- 1) Financial support by industry must be fully disclosed by the Sponsor to the participants before beginning the activity;
- 2) The program content, including slides and written material, must be determined by the Faculty planners and presenters and not the industry sponsor;
- 3) The program must deliver a balanced assessment of diagnostic and therapeutic options and promotes objective scientific discourse;
- 4) All planners and presenters must fully disclose to the audience all related financial interests; and
- 5) All CME programs must be available on equal terms to all interested practitioners, and may not be limited to attendees selected by Industry sponsor(s). Industry funding for such programs should be used to improve the quality of the education provided and not to support hospitality except for meals and only at a modest level. Industry funding may not be accepted for social events that do not have an educational component. Industry funding may not be accepted to support the costs of internal (non-CME) department meetings or retreats (either on- or off-campus).
- 6) Payment for attendance at industry-sponsored events is prohibited.

(c) Courses and Lectures at TUSM

TUSM faculty and guest speakers involved in teaching students must disclose relationships with industry that relate to the content of their course or lecture. Course directors may choose to do so only once at the beginning of the course and as necessary to avoid the appearance of bias.

The curriculum required for all first-year TUSM medical students contains a minimum of three hours of instruction devoted exclusively to the subject of Conflicts of Interest in Medicine.

(d) Scholarship and Trainee Grants

In the event that TUSM receives industry funding for scholarships or trainee funds for the medical education of medical students, it must first establish an Oversight Committee using a rotating physician chair to review and oversee all sponsorship by industry that exceeds \$10,000 in order to assess the possibility of conflicts of interest and to propose management or elimination of the conflicts.

E. *Disclosure and Enforcement of Conflicts of Interest*

(a) All TUSM faculty are required to report their relationships with Industry on an annual basis. All administrative leaders are also required to report their relationships with Industry on an annual basis.

(b) All TUSM faculty members are required to disclose relationships with industry when lecturing or otherwise teaching TUSM students. Such disclosure may occur as part of a slide presentation or as a declaration in the course syllabus or on TUSK.

(c) As to conflicts of interest related to research, all members of the research staff, including trainees, are required to disclose relationships with industry and other conflicts of interest. All TUSM faculty and students must comply with the Conflict of Interest policies set forth by the Tufts University Office of Research Administration and the Tufts University Institutional Review Board.

(d) As to Continuing Education, all TUSM speakers and planners must disclose all industry relationships and support and comply with the disclosure and resolution requirements set forth by ACCME and the Office of Continuing Education prior to implementing any TUSM-sponsored CME programs.

(e) Alleged violations of this policy shall be investigated by the TUSM Office of the Dean or Vice Dean for Academic and Clinical Affairs or the Vice Dean for Research. When indicated, such alleged violations of this policy shall be referred to the individual's dean and department chair or to the individual's immediate supervisor who shall, in conjunction with the Office of the Vice Dean determine what actions, if any, shall be taken. Such action may depend upon the seriousness of the violation, whether it is a first or repeat offense, and whether the violator knowingly violated the policy.

(f) Industry representatives who are found to violate this Policy or trespass on TUSM property will be escorted away from the premises. Other appropriate sanctions will be taken, as necessary, and their industry principals will be notified.

F. *Effective Date; Distribution and Notification*

This revised policy shall become effective as of April 5, 2010. All TUSM faculty, staff and students shall be notified of this policy and it will be posted on the TUSM website.

G. *Advisory Committee*

An Advisory Committee on Industry Conflicts of Interest has been created to review the TUSM COI policy on a regular basis and provide guidance for necessary updates and define standards for COI disclosure and management.