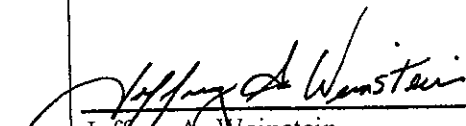
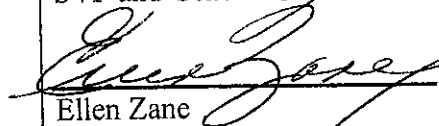


Tufts Medical Center, Inc. and the Floating Hospital for Children and Affiliates	Subject: Policy on Industry Conflicts of Interest	File Under: 2003 Section II – Organizational Policies
Issuing Department: Office of General Counsel		Latest Revision Date: April 2010
Original Procedure Date January 1998 November 2000 April 2005	Page 1 of 10	Approved By:  Jeffrey A. Weinstein SVP and General Counsel  Ellen Zane President and Chief Executive Officer

A. Introduction

Medicine today often requires the dynamic interaction between the clinician/scientist and the pharmaceutical, bio-technology and medical device industries. This policy is intended to provide a road map for the ethical and legal means of accomplishing those interactions. This policy identifies real and potential conflicts of interest between Industry and the physicians employed by Tufts MC or its affiliates, including Tufts Medical Center Physicians Organization, Inc., all Tufts – MC house staff (residents and fellows), all Tufts MC active medical staff members, all special and scientific staff, and all other Tufts MC employees that provide direct patient care, such as physician assistants, nurse practitioners, and pharmacists. The individuals will collectively be known as “Tufts MC Practitioners” for the purpose of this policy and individually as a “Tufts MC Practitioner.” Residents and fellows are included in the definition of Tufts MC Practitioners and will also be known as “House Staff” for the purpose of this policy. The policy identifies means of managing conflicts where such conflicts are manageable and for the avoidance of unmanageable conflicts of interest.

Most medical advances over the past several decades have resulted from collaborations between Industry and academia. Any policy on conflicts of interest must serve to foster continuation of such favorable relationships, while managing potential conflicts and avoiding unmanageable conflicts. It is essential that medical practice and education not be subverted by unmanageable financial conflicts, including those driven by commercial motives. It is equally important that academic medical centers, including Tufts MC, communicate to employees and House Staff the reasons for and ways of avoiding inappropriate commercial influence and to model appropriate ethical and professional behavior. At the same time, Tufts MC recognizes how essential it is to encourage and facilitate constructive relationships between Industry and health care practitioners, investigators, and educators, for the benefit of its patients and the community at large, provided these relationships comport with legal and ethical standards.

Differences exist between perceived and actual conflicts of interest. The former exists when a relationship between Industry and a Tufts MC Practitioner is established but the relationship does not undermine the Tufts MC Practitioner's unbiased conduct. Actual conflict exists when the Tufts MC Practitioner stands to gain from decisions or behavior influencing his/her primary duties or where he/she has fiduciary responsibilities to an organization doing business with Tufts MC. Both actual and perceived conflicts of interest must be identified and managed or avoided.

To this end, Tufts MC adopts the following policy:

B. Scope of Policy

(a) This policy applies to all physicians employed by Tufts MC or its affiliates (including Tufts Medical Center Physicians Organization, Inc.), Tufts – MC house staff (residents and fellows), all Tufts MC active medical staff members, all special and scientific staff, and all other Tufts MC employees that are licensed to provide direct patient care and registered to prescribe prescription drugs, such as physician assistants, nurse practitioners, and pharmacists. These individuals will collectively be known as “Tufts MC Practitioners” and individually as a “Tufts MC Practitioner” for the purpose of this policy. Residents and fellows are included in the definition of Tufts MC Practitioners and will also be known as “House Staff” for the purpose of this policy.

(b) While this policy addresses many aspects of Industry relationships, it supplements and does not supersede any existing Conflicts of Interest policies of Tufts MC (such as the Conflicts of Interest in Research policy), Tufts University School of Medicine or other institutions where Tufts MC Practitioners hold medical staff or faculty appointments.

(c) For purposes of this policy, "Industry" is defined as all pharmaceutical manufacturers, biotechnology companies, medical device² and hospital equipment suppliers and their representatives.

(d) This policy applies to Tufts MC Practitioners' interactions with employees and agents 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, except for those interactions that occur related to research. All research-related interactions between Tufts MC Practitioners and Industry are governed by the Tufts MC policy on Conflicts of Interest in Research.

C. Statement of Policy

Tufts MC recognizes that appropriate business and commercial relationships can exist between Industry and Tufts MC Practitioners, provided that they comport with legal and ethical standards. Such relationships are desirable and result in the advancement of health care knowledge and practice. It is the policy of Tufts MC that medical education, clinical and research activities must be free from influence created by improper financial relationships with, or gifts provided by, representatives of Industry. Tufts MC Practitioners are prohibited from participating in any commercial inducements (gifts, subsidies or hospitality) of any size or nature. This policy provides guidance related to specific situations, set forth in Section E below. For other circumstances, Tufts MC Practitioners should consult in advance with their

² The definition of "medical devices" as used here follows the definition contained in 105 CMR 970.000 implementing M.G.L. c. 111N, Pharmaceutical and Medical Device Manufacturer Conduct, as enacted under Chapter 305 of the Acts of 2008, An Act To Promote Cost Containment, Transparency and Efficiency in the Delivery of Quality Health Care.

Division Chief, Department Chair(s), Tufts MC's Compliance Office, Tufts MC's Office of the General Counsel or Research Administration to obtain further guidance and clarification. Charitable gifts provided by Industry in connection with fundraising done by or on behalf of Tufts MC are not covered by this Policy.

D. Conflict of Commitment

Tufts MC recognizes that the contributions and activities of an individual to the Medical Center may extend beyond the work done directly for the Medical Center. Tufts MC also understands and supports the desire of an individual, within the constraints set forth below, to earn and accept outside income for activities that do not create a conflict of interest or a conflict of commitment. Tufts MC recognizes that such activities may enhance the individual's overall professional stature, may expand his/her level of medical sophistication, and may serve to advance medical research and education.

A conflict of commitment occurs when the commitment to an individual's external activities adversely affects his or her capacity to meet his/her Tufts MC commitments. This form of conflict involves a perceptible reduction of the individual's time and energy devoted to Tufts MC activities. It is important to recognize that each individual's obligations move beyond the letter of these requirements to their spirit. Tufts MC requires that its and its affiliates' employees meet their teaching, administrative and clinical obligations, and remain productively involved in their research and other scholarly pursuits. External activities that compromise or diminish an individual's capacity to meet these obligations represent a conflict of commitment, regardless of the nature of these activities.

No Tufts MC Practitioner may accept salaried employment at another institution while employed full-time by Tufts MC. Tufts MC Practitioners may engage in consulting relationships or moonlighting arrangements subject to the approval of their Department Chair or supervisor, and subject to the additional provisions of Section E(4), below. Tufts MC Practitioners who are employed by Tufts MC on a part-time basis may not engage in consulting or other external activities during the time they have committed to Tufts MC.

E. Specific Activities

1. Gifts

Tufts MC Practitioners may 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, including those provided by Industry at professional conferences and other Non-Tufts MC Events (as defined below) and complimentary tickets to sporting or other events
- (b) Payment to attend meetings, lectures and conferences
- (c) Payment for participation in on-line CME activities.
- (d) Hospitality, whether on or off-campus, except as set forth below.

Industry choosing to make charitable contributions to Tufts MC may contact the Tufts MC Development Office. All such charitable contributions are subject to applicable policies maintained by Tufts MC.

Industry choosing to make charitable contributions to Tufts MC clinical or research department educational funds or unrestricted educational funds may contact the relevant Tufts MC Department Chair, who will coordinate with the Tufts MC Development Office or Tufts MC Research Administration, as appropriate. All such charitable contributions are subject to applicable policies maintained by Tufts MC.

2. Meals

Industry-funded meals or refreshments provided by sales or marketing representatives are prohibited on Tufts MC's campus except those in conjunction with Continuing Medical Education that comply with the standards of the Accreditation Council of Continuing Medical Education ("ACCME") or similar accreditation program with regard to content validation and means. Tufts MC will not hold any Industry-sponsored talks or lunches that do not meet such accreditation criteria. Off campus meals may be provided in accordance with Section 6(b), below.

3. Industry Supported Scientific and Educational Activities

(a) Speaking Engagements.

Tufts MC allows Industry support of scientific and educational activities that are independent of the influence and bias of the supporting company. The FDA Guidance for Industry-Supported Scientific and Educational Activities (1997) identifies and defines the several factors, *which in their totality*, are used to evaluate the activities and determine their independence.³

It is the policy of Tufts MC that these factors are satisfied with regard to speaking engagements when (1) Tufts MC Practitioners exercise independent medical judgment as to the content of the presentation⁴, (2) Tufts MC Practitioners are not prohibited by the Industry sponsor from making editorial comments on the presentation to conform the speaker's independent medical judgment

³ The factors are:

- 1) Industry control of content and selection of presenters and moderators
- 2) Disclosure of Industry support to audience
- 3) Focus of the program
- 4) Relationship between the provider and the supporting company
- 5) Provider involvement in sales and marketing
- 6) Provider's demonstrated failure to meet standards of independence, balance and scientific rigor in prior presentations
- 7) Industry support of repeated presentations
- 8) Industry influence over audience selection
- 9) Whether there are opportunities for meaningful discussion and the ability to ask questions
- 10) Dissemination of materials after the program
- 11) Whether there are any ancillary promotional activities conducted by Industry sales and marketing staff
- 12) Whether any complaints have been raised by presenters or attendees about Industry influence over the program.

⁴ Massachusetts Pharmaceutical and Medical Device Manufacturer Code of Conduct, 105 C.M.R. § 970.001.

as to the content of the presentation, and (3) the engagement is pursuant to a written agreement that meets the requirements of this policy.

(b) Authorship.

Tufts MC prohibits acceptance of services of a ghostwriter provided by Industry. Ghostwriting occurs when (1) a representative or agent of Industry 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; and (2) the contribution, including the author or contributor's relationship to Industry, 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

Tufts MC recognizes the value of consulting relationships and the benefit of making the knowledge, training and intellectual achievements of Tufts MC Practitioners available to government, business, and other organizations for the good of the community at large. Tufts MC also recognizes the potential value of these activities to Tufts MC and Tufts MC Practitioners. However, consulting arrangements that offer Tufts MC Practitioners compensation without specific, associated duties (i.e., duties such as participating on scientific advisory boards that meet regularly) are considered "gifts" and are prohibited.

In order to avoid the appearance of impropriety or remuneration or gifts disguised as consulting arrangements, Tufts MC Practitioners engaged by Industry to provide consulting services must do so pursuant to a written consulting agreement that identifies specific tasks and deliverables and contain payment provisions that are fair market value and commensurate with the assigned tasks and deliverables. Industry-funded travel pursuant to a consulting agreement is permitted so long as the travel is disclosed and the travel arrangements are not lavish.

Review and advance approval of written consulting agreements by the Tufts MC Office of the General Counsel is strongly encouraged, and is required when the Tufts MC Practitioner receives compensation from Industry under a new agreement or arrangement which provides compensation in excess of \$25,000 for a single consulting agreement or aggregate compensation of \$25,000 in two or more such transactions in a single calendar year from one Industry supporter.

5. Site Access, Use of Tufts MC Name and Resources, and Complimentary Drug Samples/Devices

(a) Industry sales representatives are not permitted in any Tufts MC area where patient care might occur except to provide training and guidance on the proper uses of pharmaceuticals, medical devices and equipment, and then, only by prior appointment.

Industry sales representatives are not permitted to interact with Tufts MC House Staff except under the direct supervision of Tufts MC physicians in a structured learning environment. Tufts MC 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 Tufts MC Physician.

(b) On-campus vendor fairs intended to showcase drugs or medical devices are permitted only with the prior approval of the Office of the General Counsel. 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 any other gifts to attendees.

(c) Tufts MC's name, facilities, and equipment are to be used solely for furtherance of Tufts MC's mission and not for the benefit of, or to imply Tufts MC's support of, non-Tufts MC activities. The name Tufts Medical Center may not be used without the express approval of the Office of the General Counsel. Except for incidental uses of telecommunications and office equipment (e.g., telephones, computers), employees, including all Tufts MC Practitioners, may not use Tufts MC resources, including facilities, equipment or information, for non-Tufts MC purposes. Specifically, Tufts MC Practitioners are not permitted to use clinical or research laboratory areas for personal gain. Tufts MC may grant permission to a Tufts MC Practitioner or other employee to use Tufts MC facilities in pursuit of outside activities or interests, but will usually do so only where there is evidence that the work will be of significant benefit to Tufts MC. Confidential information acquired through conduct of Tufts MC business or research activities may not be used for personal gain, and unauthorized access to such information may not be granted. Unless specifically authorized by the Tufts MC Practitioner's Department Chair or supervisor and the Office of the General Counsel, an individual may not use the name of Tufts Medical Center or its letterhead in sponsoring or recommending any commercial service or product.

(d) Any complimentary drug samples or medical devices received by Tufts MC must be received through the Tufts MC Pharmacy or the relevant department in accordance with the Pharmacy or relevant department's policies and procedures.

(e) On-campus demonstrations of research equipment or medical devices are permitted.

6. Continuing Medical Education

(a) *Tufts MC-Sponsored Events*

(1) All continuing education events held at Tufts MC or sponsored by Tufts MC 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 made to the appropriate clinical department. The Department Chair will determine the suitability of the Industry support, receive and account for the monetary support and distribute funds for CME-certified activities and programs through a central repository. Full documentation, including a signed commercial support agreement, is required.

(b) *Non-Tufts MC-Sponsored (Off-Campus) Events*

Industry support of off-campus CME, third-party scientific or educational conferences or professional meetings (together “Non-Tufts MC Events”), 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 Non-Tufts MC Events are not a guise for sales and or marketing activities, all Non-Tufts MC Events in which Tufts MC Practitioners attend or participate must conform to the following guidelines, as determined by the Tufts MC Practitioner’s Department Chair:

- (1) Financial support by Industry must be fully disclosed by the event sponsor to the participants before beginning the activity;
- (2) The program content, including slides and written material, must be the work product of the physician planners and presenters and not the Industry sponsor;
- (3) The program must deliver a balanced assessment of diagnostic and therapeutic options and promote objective scientific discourse;
- (4) All program planners and presenters must fully disclose to the audience all related financial interests;
- (5) If Industry provides funding to support a Tufts MC Practitioner’s attendance at a Non-Tufts MC Event, the attendee(s) must be determined by the relevant Tufts MC Department Chair or Division Chief, and may not be limited to attendees selected by Industry sponsor(s);
- (6) 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 then only at modest levels. Industry funding may not be accepted for social events that do not have an educational component; and
- (7) Industry is not permitted to pay for or reimburse Tufts MC Practitioners for the direct costs (including attendance fees, travel and lodging expenses) of attending a professional conference or other Industry-sponsored events unless the Tufts MC Practitioner is a presenter. Industry is permitted to provide grant funding to Tufts MC or Tufts MC Clinical Departments to support attendance at such non-Tufts MC Events, so long as the grant recipients are solely determined by the Tufts MC Department Chair or Division Chief.

7. Affiliations

When a person employed by Tufts MC accepts a position as an officer or a board member of another company or organization, he or she may be taking on a fiduciary duty to act in the best interests of that organization. In situations where that company or organization is doing business with, sponsoring research at, or licensing intellectual property from Tufts MC, a conflict of interest exists. Such a conflict of interest must be disclosed using the procedures set out herein and either managed or eliminated.

If an individual receives compensation for serving as an officer or a board member of another company or organization, this compensation must be fair market value and memorialized in a

written agreement that has been reviewed and approved in advance by the Tufts MC Office of the General Counsel.

F. Conflict of Interest Committee

This policy will be administered by the Tufts MC Conflict of Interest Committee (the “Tufts MC COIC”). The Chief Medical Officer will act as the Chairman of the Tufts MC COIC (the “COIC Chair”). The Tufts MC COIC shall include the Chairs of the Departments of Medicine, Surgery and Pediatrics (or their designees), the Chief Medical Officer, the Chief Scientific Officer, the Vice President of Research Administration, a representative from the Office of the General Counsel and one at-large physician member. The at-large physician member is appointed by the COIC Chair, to serve for a predetermined term. The Tufts MC COIC may meet independently or in conjunction with the Conflict of Interest committee of Tufts University School of Medicine, when reviewing a potential conflict of interest that involves a Tufts MC Practitioner who is employed by Tufts MC or one of its affiliates and is also on the faculty of Tufts University School of Medicine. The COIC Chair will bring to the attention of the Tufts MC COIC any items requiring the Tufts MC COIC’s review and make actionable recommendations to the Tufts MC COIC.

Meetings of the Tufts MC COIC may be in person or by teleconference. A quorum is comprised of 51% or more of the Tufts MC COIC membership.

G. Disclosure, Management and Enforcement of Conflicts of Interest

1. Disclosure

(a) Annual Disclosure

All Tufts MC Practitioners are required to report their relationships with Industry on an annual basis. All submissions are made to the Tufts MC Practitioner’s Department Chair or Division Chief, except that Department Chairs must submit their own disclosure forms to the Office of the Chief Medical Officer.

(b) Updated Disclosures

All Tufts MC Practitioners are required to submit updated disclosure forms prior to entering into any arrangement with Industry.

(c) Research-Related Disclosure

All Tufts MC Practitioners engaged in research and all members of the research staff, including trainees, are required to disclose relationships with Industry and other potential or real conflicts of interest on a project-specific basis pursuant to the Conflict of Interest in Research policy set forth by the Tufts MC Office of Research Administration.

(d) CME-Related Disclosure

As to Continuing Medical Education, all Tufts MC Practitioners who are presenting or planning CME events must disclose all Industry relationships and support and comply with the disclosure and resolution requirements set forth by ACCME prior to the initiation of any Tufts MC-sponsored CME programs.

2. Review of Disclosures

(a) Philosophy of Review

Tufts MC recognizes and supports appropriate business and commercial relationships between Industry and Tufts MC Practitioners that comport with legal and ethical requirements. Tufts MC also recognizes that potential conflicts of interest range in seriousness and complexity based on the scope of the business and commercial interests involved. Tufts MC will conduct reviews of all disclosures in a manner that takes into account the totality of the facts and circumstances to ensure that Industry relationships are free of improper influence and are conducted in a manner that supports the mission of Tufts MC.

(b) Initial Review by Department Chair/Division Chief or Office of the General Counsel

Department Chairs/Division Chiefs provide initial review of all annual disclosures submitted by Tufts MC Practitioners, except that the Chief Medical Officer reviews annual disclosures made by Department Chairs/Division Chiefs. In instances where the disclosure form discloses no conflicts and/or only requires a straight-forward and modest plan to reduce, eliminate or manage the potential conflict, the Department Chair/Division Chief or the Chief Medical Officer, as the case may be, may elect to conduct an expedited review in conjunction with the Office of General Counsel. These actions are reported to the entire Tufts MC COIC on a quarterly basis by the Department Chair/Division Chief and Office of the General Counsel so that all expedited reviews are shared with the membership of the Tufts MC COIC.

(c) Additional Review by Tufts MC COIC Chair and Office of General Counsel

Where a Division Chief has questions about a disclosure he or she will first confer with the Department Chair. When the question remains open after this consultation, or when the Department Chair/Division Chief/Chief Medical Officer and/or Office of the General Counsel, as the case may be, determine that the disclosed activity poses a potential conflict of interest, the Department Chair/Division Chief/Chief Medical Officer and/or Office of the General Counsel will prepare an information packet for review by the COIC Chair. The COIC Chair will contact the Tufts MC Practitioner who will have an opportunity to present additional information.

Based on the information provided, the COIC Chair may recommend that i) the conflict be eliminated, ii) the proposed activity be prohibited, or iii) a conflict of interest management plan be implemented.

3. Management or Elimination of Conflicts

If the COIC Chair recommends that management or elimination of a conflict is required, such a plan shall be prepared by the COIC Chair in collaboration with the Office of the General Counsel. The plan recommended by COIC Chair and the Office of the General Counsel must be reviewed and approved by the Tufts MC COIC. Subject to the appeal to the Tufts MC CEO as outlined in section 4 below, the decisions of the Tufts MC COIC will be final. The COIC Chair will communicate the decision of the Tufts MC COIC to the Department Chair/Division Chief and to the Tufts MC Practitioner involved.

(a) Management of Conflicts of Interest

The following are examples of conditions or restrictions that may be recommended by the Tufts MC COIC to manage or eliminate conflict:

- Public disclosure of the conflict of interest;
- Monitoring of proposed activity by independent reviewers;

- Disqualification from participation in all or a portion of the activity related to the conflict;
- Divestiture of financial interests that give rise to the conflict; or
- Severance of relationships that create actual or potential conflicts.

An example of a conflicts of interest management plan could entail the following:

- Disclose the Tufts MC Practitioner's financial relationship with Industry.
- Describe the steps taken to inform current or new House Staff and other trainees of the conflict of interest.
- Demonstrate how publications and meeting presentations are handled to allow the co-existence of Industry and academic goals.

The foregoing list is for demonstration purposes only and is not intended to be complete or limit the measures utilized to manage or eliminate conflicts of interest.

Conflicts of interest management plans are reviewed annually by the COIC Chair.

(b) Elimination of Conflicts of Interest

Where the Tufts MC COIC determines that a management plan cannot appropriately manage the conflict of interest, it may require that the conflict be eliminated or that the proposed activity not proceed. Factors in this decision may include the nature and significance of the conflict, the potential for having an adverse impact on the scientific field or on the reputation of Tufts MC, and/or the level of difficulty involved in managing the conflict relative to the benefit of the proposed activity.

4. Appeal of Determination Made by Tufts MC COIC

Decisions of the Tufts MC COIC may be appealed to the Tufts MC President and CEO, whose decision on these matters is final.

5. Enforcement of this Policy

(a) Alleged violations of this policy shall be investigated by the Tufts MC Office of the General Counsel. When indicated, such alleged violations of this policy shall be referred to the individual's Department Chair and to the individual's immediate supervisor who shall, in conjunction with the Office of the General Counsel 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.

(b) Industry representatives who are involved in the violation of this policy or who trespass on Tufts MC property will be escorted from the premises and may be prohibited from further interaction with Tufts MC Practitioners. Other appropriate sanctions will be taken, as necessary, and their Industry principals may be notified.

H. *Effective Date; Distribution and Notification*

This policy shall become effective as of April 16, 2010. All Tufts MC Practitioners and staff shall be notified of this policy and it will be posted on the Tufts MC website.