

Conflicts of Interest in Academic Medicine

Revised TUSM Policy on Industry Conflicts of Interest

**Tufts University School of Medicine
Effective April 5, 2010**

Industry Conflicts of Interest

What is an Industry Conflict of Interest?

- **A industry conflict of interest exists when a TUSM faculty member has a relationship (particularly financial) with industry that might reasonably appear to influence his or her research, teaching, prescribing habits or other professional responsibilities.**

Industry Conflicts of Interest

- Potential conflicts of interest occur when an individual receives compensation from an Industry sponsor (e.g. pursuant to a consulting arrangement, stock ownership, speaking engagement) and such individual also promotes that sponsors products through prescriptions (on or off-label), continuing education, talks or by undertaking human subject research on behalf of the Industry sponsor.

Industry Conflicts of Interest

- The term “conflict of interest” has come to encompass a wide array of physician-industry relationships, ranging from important collaborations that discover new pharmaceutical products to improper marketing ploys intended solely to influence physician prescribing habits.

Industry Conflicts of Interest

- TUSM values legitimate faculty-industry collaborations intended to discover, develop, test, produce and commercialize new pharmaceutical products.

Industry Conflicts of Interest

- TUSM prohibits industry relationships wherein physicians use TUSM credentials to give credibility to industry products and practices solely for the purpose of marketing, promoting or influencing the prescribing practices of other physicians.

Industry Conflicts of Interest

“Conflicts of interest are ubiquitous and inevitable in academic life, indeed, in all professional life. The challenge for academic medicine is not to eradicate them, which is fanciful and would be inimical to public policy goals, but to recognize and manage them sensibly and effectively.”

David Korn *JAMA* 284, 2234-2236, 2000

Industry Conflicts of Interest

The goal of the TUSM Conflict of Interest policy is to provide guidance to the TUSM community in (1) recognizing the prevalent forms of industry relationships; (2) eliminating improper influence, particularly through marketing; and (3) supporting the legitimate role of physicians in academic medicine.

Background:

The Need for Collaboration

- Prior to 1980 the federal government sponsored research that led to hundreds of valuable patents.
- However, many of these patents sat idle for years because the federal government, which owned the rights, lacked the resources and relationships with industry needed to develop and market the inventions.

Background: Bayh-Dole Act of 1980

Federal legislation known as the Bayh-Dole Act was enacted in 1980 to respond to this issue by promoting the commercialization of funded research.

Bayh-Dole Act of 1980

The Bayh-Dole Act created a uniform patent policy among federal agencies that fund research enabling non-profit organizations and small businesses, including universities, to retain titles to inventions made pursuant to federally-funded research programs.

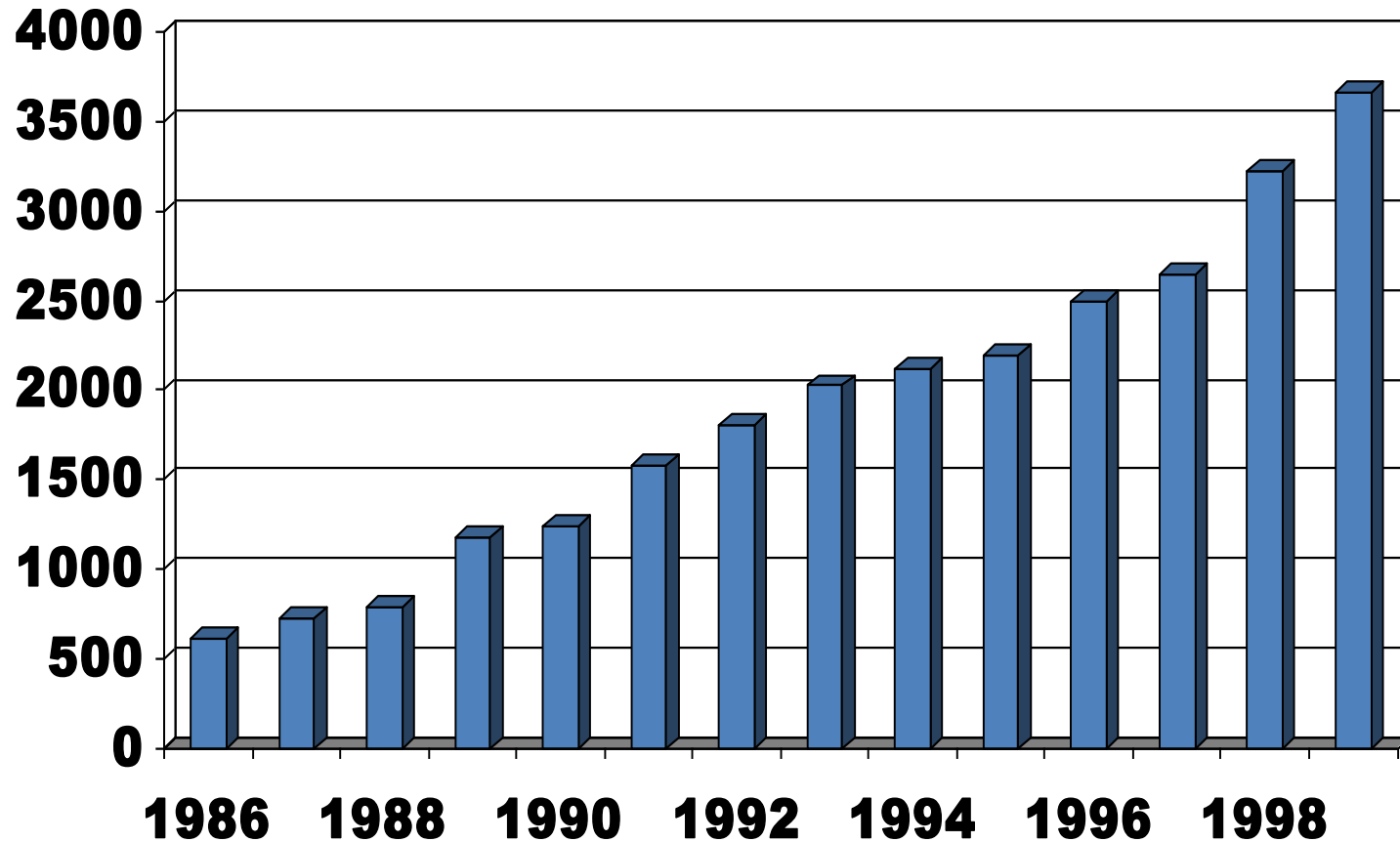
The Bayh-Dole Act was thus designed to promote the use, development and promotion of technology invented with federal funding.

Bayh-Dole Act of 1980

- Recipients of federal funding now have the right to retain ownership of inventions developed with federal funding.
- Recipients of funds must also share royalties and other income derived from the invention with the inventor(s).
- Result: Investigators and institutions are encouraged to seek technology transfer (commercial) opportunities – *i.e., bring inventions to market.*

Patents to Universities 1986-1999

Source: Association of University Technology Managers



Industry Conflicts of Interest

TUSM encourages legitimate industry relationships. This policy is intended to:

- Educate faculty and students about conflicts of interest that can arise through these and other relationships and the importance management;
- Protect the integrity of TUSM research (including subjects) and education;
- Comply with national standards for proper disclosure of industry relationships;
- Distinguish improper marketing relationships.

Industry Conflicts of Interest

To whom does the policy apply?

- All individuals who hold a TUSM faculty or administrative appointment, including those with staff appointments at affiliated hospitals.
- All TUSM medical students.
- TUSM-affiliated hospitals are urged to maintain COI policies that are consistent in addressing faculty and student relationships with Industry.

Industry Conflicts of Interest

- TUSM faculty involved in research must comply with the Conflict of Interest regulations set forth by the Tufts University Office of Research Administration.
- This policy shall not be construed to replace or supersede any of the requirements or disclosures set forth in those regulations.

Industry Conflicts of Interest

- Massachusetts law (Chapter 111N) also regulates Conflicts of Interest within the Commonwealth of Massachusetts.
- The TUSM policy is consistent with Massachusetts law.

Gifts

- The provision of gifts from industry to physicians does not serve to further legitimate physician-industry collaborations.
- Gifts of every nature, whether they be pens, mugs, complimentary lunches or industry-funded expenses for educational events, are intended solely to market industry products.

TUSM Policy: Gifts

TUSM Faculty and students may not accept gifts of any nature or amount from representatives of Industry, including:

- **Free items such as pens, mugs, totes, pharmaceutical samples for personal use.**
- **Faculty may not receive payment to attend meetings, lectures and conferences (including online) solely as a participant.**

TUSM Policy: Gifts

- Hospitality, on or off-campus (*e.g.*, complimentary tickets to sporting or other events), is prohibited.
- Industry seeking to make charitable contributions to TUSM may do so through the TUSM Development Office, subject to its procedures.

TUSM Policy: Meals

Industry-funded meals, except modest meals provided in conjunction with approved on- or off-campus CME or other educational activities, or pursuant to consulting arrangements, are prohibited.

TUSM Policy: Meals

The following are examples of activities not acceptable for TUSM physicians:

- Coffee and donuts, courtesy of ABC Corp., brought into a physicians' lounge in the Medical Center's Department of X.
- Chinese food provided by an XYZ Corp. representative for a luncheon talk in the Medical Center's Department of Y.

TUSM Policy: Travel Funds

- Industry-funded travel, except in conjunction with a consulting contract or for a CME presenter, is prohibited.
- Physicians and trainees are otherwise prohibited from accepting “direct” funds from Industry for attending scientific meetings. Industry can fund attendance by contributing to a central repository and allowing TUSM to assess suitability, identify recipients and distribute funds.

TUSM Policy: Travel Funds

The following travel funds are not permitted for TUSM physicians:

- ABC Corp, maker of new drug to treat condition Q, offers to pay the admission fee for certain members of the Medical Center to attend a conference on the treatment of Q.

TUSM Policy: Speaking for Industry

TUSM faculty may not participate in industry-sponsored speaking activities, whether or not compensated, if the content and materials (e.g. slides) are prepared or controlled by the industry sponsor.

TUSM Policy: Speaking for Industry

Academic investigators may present results of their own industry-sponsored studies only when there is full opportunity to present balanced research and a forum for critical exchange with the audience is afforded to the speaker.

TUSM Policy: Ghostwriting

- Ghostwriting occurs when Industry prepares written promotional materials in whole or in substantial part and such materials are attributed to a non-industry author.
- Ghostwriting is prohibited at TUSM.

TUSM Policy: Consulting Relationships

- Consulting arrangements that offer guaranteed compensation without specific, associated duties (*e.g.* scientific advisory boards that meet regularly) are tantamount to “gifts” and thus prohibited.
- Consulting services are permissible when arranged pursuant to a contract defining tasks and deliverables with payment commensurate to the tasks.

TUSM Policy: Consulting Relationships

The following consulting arrangement is permitted:

- Dr. Jones sits on XYZ's scientific advisory board and receives less than \$10,000 per year as a consultant.
- Dr. Jones (TUSM faculty) seeks to act as PI for XYZ Corp. at a local test site testing a new blood pressure medication. The affiliated medical center is paid per subject enrolled.
- The study is administered by a contract research organization (with firewall, if indicated) and managed by a Data Safety Monitoring Board.

TUSM Policy: Consulting Relationships

The following consulting arrangement is suspect:

- Dr. Jones (TUSM faculty) seeks to act as PI at a medical center as local test site for XYZ Corp. testing the same medication. The medical center is paid per subject enrolled.
- Dr. Jones has a leadership role on XYZ's scientific advisory board and receives more than \$10,000 per year as a consultant.
- Dr. Jones owns stock in XYZ Corp. with a par value of more than \$10,000; a patent for this subject blood pressure medication is pending.

TUSM Policy: Industry Access to TUSM

- **Industry representatives are not permitted to interact with TUSM students except under the direct supervision of TUSM faculty in a structured learning environment.**
- **Industry representatives will not be provided with email addresses or mail distribution lists.**

TUSM Policy: Industry Access to TUSM

- On-campus exhibits intended to showcase Industry products are permitted only with prior approval of the Dean or Vice Dean.
- On-campus demonstrations of research equipment prior to purchase are permitted, consistent with TUSM purchasing policies.
- Exhibitors must not be permitted to distribute free samples, meals, raffle tickets or other gifts to attendees.

TUSM Policy: Complimentary Samples

- Complimentary drug samples are prohibited at TUSM.
- Complimentary medical devices are prohibited at TUSM.

TUSM Policy: Medical Education

- All Course Directors who teach TUSM students must disclose to students all relevant relationships with industry.
- Course directors are responsible for full disclosure by their guest speakers.
- Disclosure may be undertaken verbally but must also occur on the course syllabus, TUSK or on the lecturer's slide presentation.
- Disclosure should occur at the beginning of the course and when relevant to the content of the course materials.

Example of Disclosure: Medical Education

Jonathan Smith, M.D.

Associate Professor, Dept. of X, TUSM

Consultancies:

Major Pharmaceuticals, Inc.

Specialty Products Corp.

Funded Research

Major Pharmaceuticals, Inc.

Founding Partner and Shareholder

ABC Start-up Corp.

TUSM Policy: Medical Education

- Conflicts of Interest in medicine is now incorporated into the first-year medical school curriculum.
- TUSM students receive a minimum of 3 hours of education devoted to industry conflicts of interest using evidence-based research.
- TUSM faculty are invited to an annual COI Symposium.

TUSM Policy: Continuing Medical Education

- All CME events hosted or sponsored by TUSM must comply with the ACCME Standards for Commercial Support of educational activities, whether or not CME credit is awarded.
- Industry support for TUSM-sponsored CME are handled by the Office of Continuing Education to address suitability of industry support, account for it, and distribute funds for ACCME-certified educational activities.
- OCE can designate CME funds to go directly to joint sponsors. Documentation is required.

TUSM Policy: Continuing Medical Education

- Industry sponsors may not designate CME program faculty, participants or content. All CME programs must be available on equal terms to all interested attendees.
- CME speakers and planners must disclose industry relationships and commercial support.
- Industry funding may not be accepted to support the costs of internal (non-CME) department meetings or retreats, either on- or off-campus.

TUSM Policy:

Continuing Medical Education

- TUSM faculty who choose to attend off-campus, non-ACCME educational activities are urged to evaluate the potential for undue industry influence using the guidelines set forth in Section 6(B) of the TUSM Policy.
- Payment for attendance (only) at industry-sponsored events is prohibited.

Managing Conflicts of Interest

- **The Office of Research Administration continues to manage Conflicts of Interest involving research matters.**
- **The Office of Continuing Education continues to manage all potential conflicts of interest relating to the implementation of any TUSM-sponsored CME programs.**

COI Advisory Committee

- **The COI Advisory Committee on Industry Relationships establishes COI policy and provides standards and guidance for COI disclosure and management of relationships.**
- **The COI Advisory Committee oversees annual collection of COI data.**

COI Advisory Committee

- The COI Advisory Committee has representatives from the basic sciences, public health and community medicine, all clinical departments and each of the major affiliates.
- In 2010 the COI Advisory Committee is chaired by Paul Summergrad, MD.

COI Management Options

The following are some options available to manage potential conflicts:

- Disclosure of financial interests to students and research subjects.
- Disclosure of financial interests in publications and presentations.
- Reduction/elimination of financial interests to accepted thresholds.

Disclosure of Industry Relationships

- All TUSM faculty and administrators must report their relationships with Industry on an annual basis.
- The Office of COI Administration will provide forms and review disclosures.
- The COI Advisory Committee will oversee COI reporting and management.
- TUSM-affiliated institutions are urged to adopt consistent COI policies.

Disclosure of Industry Relationships

- The Office of COI Administration will make every effort to assist faculty in fostering and managing industry relationships.
- Email: med-coi@tufts.edu
- Consulting contracts will not be reviewed unless specifically requested.

Management of Conflicts

- Potential conflicts identified on TUSM Disclosure Forms will be managed by the Office of COI Administration.
- When a potential conflict is identified, the faculty member will be notified.
- The appropriate Dean or Department Chairs may be asked to assist in the management process.

TUSM Policy: Violations

- Conflicts that cannot be managed informally will be referred to the COI Advisory Committee.
- Suspected COI violations also may be reported to the Office of the Dean or the TUSM faculty member's affiliated institution.

TUSM Policy: Violations

- **The Dean of Student Affairs will be responsible for dealing with students who violate this policy.**
- **Industry representatives who violate this Policy or trespass on TUSM property will be escorted away from the premises and reported to their principals.**

For More Information:

- A list of *Frequently Asked Questions* is posted on the COI Website.
- A list of *Resources* is posted on the COI website.
- Specific inquiries can be emailed to: med-coi@tufts.edu.