

Introduction

The faculty¹ and medical students of the Joan C. Edwards School of Medicine (SOM) have responsibilities for patient care, education, and research. While carrying out these responsibilities, the faculty and medical students are expected to uphold the highest standards of professional integrity. It is the purpose of this policy to define the relationship between Industry² and the SOM in order to avoid conflicts of interest (COI)³ that could potentially endanger or be perceived to endanger patient safety, the integrity of our education and training programs, data integrity, or the reputation of our institution.

While the interaction with Industry can be beneficial, Industry influence can also result in unacceptable conflicts of interest that may lead to increased costs of healthcare, compromise patient safety, negative socialization of students and residents, bias of research results, and diminished confidence and respect among patients and the general public. Because provision of financial support or gifts, even in modest amounts, can exert a subtle but measurable impact on recipients' behavior, the SOM has adopted the following policy to govern the interactions between Industry and the SOM faculty and its medical students.

Statement of Policy

It is the policy of the SOM that clinical decision-making, education, and research activities are free from influence created by improper relationships with Industry.

Specific Activities

A. Gifts

SOM faculty and medical students shall not accept or use gifts (including meals and hospitality) from representatives of Industry, regardless of the nature or dollar value of the gift. Gifts of nominal value may not violate professional standards or laws; however, such gifts do not improve the quality of patient care, add unnecessary costs to the healthcare system, and may subtly influence clinical decisions. Gifts that incorporate a company logo introduce a marketing presence that is not appropriate to a non-profit educational healthcare system. SOM faculty and medical students may not accept meals or other hospitality funded by Industry. Industry wishing to make charitable

¹ For this policy "faculty" will refer to faculty, senior administrative staff and trainees of the SOM and University Physicians and Surgeons (UP&S)

² "Industry" is defined as representatives of the pharmaceutical, biotechnology, medical device, and hospital supply industries.

³ "Conflict of Interest" will be defined as published by the Institute of Medicine as a set of circumstances that creates risk that professional judgment or actions regarding a primary interest be unduly influenced by a secondary interest. Primary interests include promoting and protecting research integrity, welfare of patients, and quality of medical education. Secondary interests include financial gain, desire of professional advancement, recognition for personal achievement, and favors to friends, family or colleagues.

contributions to the SOM may contact the SOM Development Officer or contact the Marshall University Foundation. This donation could be designated for anonymously sponsored meals for educational events (e.g. Journal Club). Modest meals provided incidental to attendance at an off-site event as described below (Industry Sponsored Meetings) may be acceptable.

B. Drug or Device Samples

The provision of free samples by manufacturers provides assistance to some patients to quickly begin a course of treatment or determine which therapeutic option is most effective for that patient. While societal benefits result from the availability of medications at the point of care, sampling, on the other hand, may result in regulatory and security concerns, poses potential safety risks with professional liability exposure, and encourages prescribing of new, high priced medications whose efficacy may not be different from existing treatments. In addition, the manufacturers' cost of producing and packaging the samples introduces a substantial expense into the overall consumer cost. In addition, the physician's practice expense associated with the storing and managing of the samples may increase the provider costs.

At this time, the SOM has no structured approach for the handling and distribution of sample medications. For this reason, at the current time, free drug or device samples may not be accepted at the SOM. There may be an exception made allowing for the distribution of a drug or device to a rare patient who, in the physician's judgment, has needs, both medical and financial, that cannot be fulfilled by the usual pathway. For this exception the physician should have the approval of the department chair with a written report on file outlining the safe storage and distribution of the sample.

C. Site Access by Sales and Marketing Representatives

Sales and marketing representatives are not permitted in any patient care areas except to provide in-service training on devices and other equipment and then only by appointment. Sales and marketing representatives are permitted in non-patient care areas by appointment only. Interactions with representatives of Industry are appropriate as it relates to exchange of scientifically valid information, interactions designed to enhance continuity of care for patients, as well as training intended to advance healthcare. Refreshments and gifts from vendors, however modest, are prohibited during visits by Industry representatives.

D. Consulting Relationships

There is a potential for a COI in any business relationship between a member of the SOM faculty/medical student and an outside company or organization. Relationships can take many forms, including: membership on boards of directors or scientific advisory boards; review/evaluation of efficacy of new products or devices for vendors; consulting with institutions on behalf of a vendor; expert witness testimony; "moon-lighting"; etc. The SOM recognizes the obligation to make the knowledge of its faculty members and medical students available to government, business, and civic organizations. However, consulting arrangements that pay faculty/medical student a guaranteed amount without associated duties shall be considered gifts and are

prohibited. In order to avoid gifts disguised as consulting contracts, the contracts must provide specific tasks and deliverables, with payment commensurate with the tasks assigned. All such relationships with Industry or outside organizations may be entered into only with the prior permission of the department chair and fully disclosed on the annual COI Questionnaire. In addition, SOM faculty are obligated to comply with Marshall University's policy on Conflict of Interest (MUBOG-GA-12).

E. Industry Sponsored Meetings or Industry Support for Off-Campus Meetings

SOM faculty and medical students, may participate in or attend Industry-sponsored meetings, or other off-campus meetings where Industry support is provided, so long as: (1) the activity is designed to promote evidence-based clinical care or advance research; (2) the financial support of Industry is prominently disclosed; (3) attendees do not receive gifts or other compensation for attendance; (4) meals provided are modest and consistent with the educational purpose of the event. In addition, if a SOM representative is participating as a speaker; 1) All lecture content is determined by the SOM speaker and the speaker makes clear that the views expressed are the views of the speaker and not the SOM; 2) compensation is reasonable and limited to reimbursement of reasonable travel expenses and a modest honorarium not to exceed reasonable and customary.

F. Speaker Bureaus and Ghostwriting

While one of the most common ways to disseminate new knowledge is through lectures, "speaker bureaus" sponsored by Industry may serve as little more than an extension of the marketing department. Before committing to being a speaker at an Industry-sponsored event, careful consideration should be given to whether the event meets the criteria set forth in the above section of this policy.

Under no circumstances may SOM faculty or medical students be listed as co-authors on papers ghostwritten by Industry representatives. SOM faculty and medical students should always be responsible for the content of any papers or talks that they give.

G. Support of Continuing Medical Education (CME)

Industry/Commercial support of CME can provide benefit to patients by ensuring that the most current evidence-based medical information is provided to practitioners. In order to ensure that potential bias is minimized and that CME activities are not used for marketing, all CME activities hosted or sponsored by the SOM must comply with the ACCME Standards for Commercial Support, standards to insure the independence of CME activities. All such agreements for commercial support must be negotiated through and executed by the Department of CME of the SOM. Industry/commercial funding for such programming should be used to improve the quality of the education provided and should not be used to support hospitality, such as meals, social activities, etc., except at a modest level. Industry funding may not be accepted to support the costs of department meetings or retreats (either on- or off-campus).

H. Industry Support for Scholarships or Fellowships or Other Support of Students, Residents, or Trainees

Industry support for scholarships and fellowships must comply with all University and SOM requirements for such funds. Selection of recipients will be completely within the discretion of the SOM. Support for these activities should be approved by the Marshall University Research Corporation, the Dean, or his designee. Industry support for other trainee activities, including travel expenses must be accepted into a common pool of discretionary funds, which shall be maintained by the Dean of the SOM. Attendees must be selected by the dean and department chair based on merit and financial need.

I. Patient Referrals

SOM physicians refer patients to outside companies for services such as home care, home nutritional support, direct pharmacy services, etc. These companies do not necessarily sell products or services to the SOM or its physicians. However, they depend on the SOM for their business through patient referrals, for which they bill the patients or carriers directly. The SOM cannot accept gifts in any form from these vendors in exchange for such referrals. Such gifts would constitute illegal kickbacks. Any gifts or donations offered by these companies must be directed to the SOM Development Officer or Marshall University Foundation for review to ensure compliance with all regulatory requirements.

J. Purchasing Decisions

All purchasing decisions must be made in order to promote the best interests of the SOM and our patients. SOM faculty and staff involved in decisions regarding the purchase of equipment or supplies must disclose any financial interest they have with vendors on the annual COI Questionnaire. Anyone with a COI may not participate in discussions and decisions on purchases from a company in which they have a financial interest or purchase of products of a competitor of the company in which they have a financial interest. Occasionally, vendors offer an incentive if a buyer agrees to purchase the company's goods or services. Personal incentives are considered gifts and cannot be accepted under any circumstances. A vendor may offer the SOM or individual departments a discount on the purchase price of a product. The department or school will only consider any discount as a factor in the formal purchasing/bidding process.

Vendors may offer to place a new device or piece of equipment on-site on a trial basis. Such arrangements require the SOM Department of Finance & Administration approval of a no-charge Purchase Order that describes the item and timeframe for evaluation. The vendor is expected to deliver and retrieve the item.

K. Individual Conflict of Interest in Research

Guidelines for COI in research are defined in "Marshall University Board of Governors Policy No. AA-41." All SOM faculty, medical students and staff involved in research will be required to complete the annual on-line "Significant Financial Interest Disclosure-Confidential Personnel Form." Support for all research activities should be approved by the Marshall University of Research Office, the Dean or his designee.

L. External teaching or research engagements

Faculty who wish to be engaged in teaching or research activities that fall outside of the normal scope of their roles and responsibilities within the SOM, should seek approval from their department chair and any financial reimbursements must be reported in the Marshall Health "Significant Financial Interest Disclosure Personell Form". Furthermore, these external engagements should be reviewed every two years by the department chairs, the Dean or his designee to ensure that they do not compromise the internal teaching and research activities.

M. Reporting and Enforcement

All material information disclosed will be provided jointly to the office of Research Integrity at Marshall University and the Office of Compliance and Risk Management at the SOM. Information requiring clarification will be managed through the relevant department chair. Any significant COI will be referred to the Vice President and Dean for Health Sciences or his/her designee. SOM faculty, medical students and personnel are required to know and abide by the applicable SOM policies and, if needed, adhere to plans to manage or monitor conflicts as determined by the appropriate officials including the President, Vice President and Dean for Health Sciences, Vice President for Research or their designees.

Violations of this policy by SOM faculty and/or medical student may result in any of the following actions depending upon the seriousness of the violation, whether the violation is the first or repeat offense, and whether the violator knowingly violated this policy or attempted to hide the violation: 1) Counseling the individual involved; 2) Written reprimand, entered into the faculty/medical student record; 3) Banning the violator from any further outside engagements for a period of time; 4) Requiring the violator to return any monies received from the improper outside relationship; 5) Requiring the violator to complete additional training on COI; 6) Termination for cause.

Any disciplinary action taken hereunder shall follow the established procedures of the University and/or the SOM.

N. Other conflict or interest or related policies

All faculty and staff are also required to abide by and be aware of the following additional policies concerning conflicts of interest:

- i) Marshall University General Conflict of Interest (MUBOG-GA-12)
- ii) Institutional Conflict of Interest in Research (MUBOG-AA-44)
- iii) Individual Conflict of Interest in Research (MUBOG-AA-41)
- iv) Marshall Health Singficant Financial Interest Disclosure
- v) *Marshall Health Faculty Income policy*

Adopted by the Clinical Practice Management Committee: 11/16/2010

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