

	MOREHOUSE SCHOOL OF MEDICINE/MOREHOUSE MEDICAL ASSOCIATES, INC. OFFICE OF COMPLIANCE AND INTERNAL AUDIT POLICY AND PROCEDURE MANUAL	POLICY NUMBER	COMPLIANCE
		EFFECTIVE DATE	7-3-2009
	<u>POLICY</u> POLICY AND GUIDELINES FOR INTERACTIONS WITH PHARMACEUTICAL, BIOTECHNOLOGY, MEDICAL DEVICE AND HOSPITAL AND RESEARCH EQUIPMENT SUPPLY INDUSTRY	SUPERSEDES	5-1-97

OVERVIEW:

The Morehouse School of Medicine and Morehouse Medical Associates, Inc. ("MSM") is dedicated to improving the health and well-being of individuals and communities; increasing the diversity of the health professional and scientific workforce; and addressing primary health-care needs through programs in education, research, and service, with emphasis on people of color and the underserved urban and rural populations in Georgia and the nation. This shared mission requires that faculty, students, trainees, and staff of MSM interact with representatives of the pharmaceutical, biotechnology, medical device, and hospital equipment supply industry ("Industry"), in a manner that advances the use of the best available evidence so that medical advancements and new technologies become broadly and appropriately used. 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 of patient safety, negative socialization of students and trainees, bias of research results, and diminished confidence and respect among patients, the general public and regulatory officials. Because provision of financial support or gifts, even in modest amounts, can exert a subtle but measurable impact on recipients' behavior, MSM has adopted the following policy to govern the interactions between Industry and MSM personnel.

There is a growing body of evidence demonstrating the adverse consequences of interactions between healthcare providers and Industry, including practices such as receipt of small gifts that have traditionally been considered acceptable by professional standards, such as the ethical opinions of the American Medical Association's Council on Medical and Judicial Affairs. While healthcare professionals may not believe that they are personally biased by Industry, retailing by Industry representatives is designed to sell products and advance the interests of Industry's shareholders. This policy has been designed on the basis of the best available literature on conflict of interest and is intended to provide a set of guiding principles that members of the MSM community as well as representatives of Industry can use to assure that their interactions result in optimal benefit to clinical care, education and research, and maintenance of the public trust. This policy is designed to affect the behavior and practices of Industry, as much as the behavior of MSM personnel. While partnerships between industry and physicians may further mutual interests to improve clinical management of diseases and improve patient care, the provision of gifts, food, or other blandishments add nothing to the substance of the exchange, and leave both parties subject to questions of integrity and commitment to professional practice responsibilities.

PURPOSE:

This policy is established to provide guidelines for interactions with industry representatives for medical staff, faculty, staff, residents, students, and trainees of MSM. Interactions with industry occur in a variety of contexts, including marketing of new pharmaceutical products, medical devices, and research equipment and supplies on-site, on-site training of newly purchased devices, the

development of new devices, educational support of medical students and trainees, and continuing medical education. Faculty and trainees also participate in interactions with industry off campus and in scholarly publications. Many aspects of these interactions are positive and important for promoting the educational, clinical and research missions of MSM. However, these interactions must be ethical and cannot create conflicts of interest that could endanger patient safety, data integrity, the integrity of our education and training programs, or the reputation of either the faculty member or the school.

SCOPE OF POLICY:

This policy applies to all medical staff, faculty, staff, residents, interns, students, and trainees of MSM. While this policy addresses many aspects of Industry interaction, it supplements the existing conflict of interest policies of MSM, particularly as they apply to research conflicts of interest:

- Institutional Conflicts of Interest
- Individual Conflicts of Interest
- Research Conflicts of Interest

In all cases where this policy is more restrictive than other MSM conflict of interest policies, this policy shall control.

This policy applies to interactions with all sales, marketing, or other product-oriented personnel of Industry, including those individuals whose purpose is to provide information to clinicians about company products, even though such personnel are not classified in their company as "sales or marketing."

STATEMENT OF POLICY

It is the policy of MSM that clinical decision-making, education, and research activities be free from influence created by improper financial relationships with, or gifts provided by, Industry. For purposes of this policy, "Industry" is defined as all pharmaceutical manufacturers, and biotechnology, medical device, and hospital and research equipment supply industry entities and their representatives. In addition, clinicians and their staffs should not be the target of commercial blandishments or inducements – great or small – the costs of which are ultimately borne by our patients and the public at large. These general principles should guide all potential relationships or interactions between MSM personnel and Industry representatives. The following specific limitations and guidelines are directed to certain specific types of interactions. For other circumstances, MSM personnel should consult in advance with their deans or department chairs or administrative management to obtain further guidance and clarification. Charitable gifts provided by industry in connection with fundraising done by or on behalf of MSM shall be subject to other policies adopted from time to time by MSM or foundations fundraising on their behalf.

SPECIFIC ACTIVITIES

1. Gifts and Provision of Meals

MSM personnel are prohibited from accepting or using personal gifts (including food) from representatives of Industry, ***regardless of the nature or dollar value of the gift.*** Although personal gifts of nominal value may not violate professional standards or anti-kickback laws, such gifts do not improve the quality of patient care, may subtly influence clinical decisions, and add unnecessary costs to the healthcare system. Gifts from Industry that incorporate a product or company logo on the gift (e.g., pens, notepads, stethoscopes,

journals, textbooks, or office items such as clocks) introduce a commercial, marketing presence that is not appropriate to a non-profit educational and healthcare system. Meals or other hospitality funded directly by Industry may not be offered in any facility owned and operated by MSM, except as outlined in subsection 5 below.

MSM personnel may not accept meals or other hospitality funded by Industry, whether on-campus or off-campus, or accept complimentary tickets to sporting or other events or other hospitality from Industry. Modest meals provided incidental to attendance at an off-campus event that complies with the provisions of subsection 6, below, may be accepted. Industry wishing to make charitable contributions to MSM may contact the Office of Institutional Advancement. Such contributions shall be subject to any applicable policies maintained by MSM, and the receiving organizations.

2. Consulting Relationships

MSM recognizes the obligation to make the special knowledge and intellectual competence of its faculty members available to government, business, labor, and civic organizations, as well as the potential value to the faculty member, and MSM.

However, consulting arrangements that simply pay MSM personnel a guaranteed amount without any associated duties (such as participation on scientific advisory boards that do not regularly meet and provide scientific advice) shall be considered gifts and are consequently prohibited.

In order to avoid gifts disguised as consulting contracts, where MSM personnel have been engaged by Industry to provide consulting services, the consulting contract must provide specific tasks and deliverables, and must be restricted to scientific issues. The compensation paid must be reasonable and reflect fair market value for the service and time provided, and must be commensurate with the tasks assigned. All such arrangements between individuals or units and outside commercial interests must be reviewed and approved prior to initiation in accordance with appropriate MSM policies.

For MSM personnel, consulting relationships with Industry may be entered into only with the prior permission of a faculty member's dean, department chair or administrative management. In addition, prior review and written approval from the faculty member's dean is required if consulting relationships with any one company (including the parent and subsidiary companies) will pay the faculty member in excess of \$10,000 in any twelve-month period. For employees of MSM who are not faculty, prior written approval of the appropriate supervisor is required for any outside consulting. MSM reserves the right to require faculty and employees to request changes in the terms of their consulting agreements to bring those consulting agreements into compliance with MSM policies.

3. Drug or Device Samples

The provision by manufacturers of "free" samples of prescription drug or device products is a marketing practice designed to promote the use of these products and to gain access to prescribers to influence their behavior. Studies from the literature quite convincingly demonstrate the effectiveness of this technique to boost sales. At the same time, this practice provides invaluable assistance to some patients to quickly begin a course of treatment or to determine which therapeutic option is most beneficial for that patient. Free samples also have

been responsibly incorporated into the evidence-based decision making of some individual and group practices. While societal benefits result from the availability of medications at the point of care, pharmaceutical samples are not preferred as often their prior storage and handling are suspect (temperature/humidity control), accountability is generally low (pilferage, diversion, theft), documentation is usually weak (incomplete logs), patient directions and patient information are not provided and/or are inadequate, and pharmacist review/profiling is left incomplete.

Therefore, with limited exceptions, sample medications are not permitted in MSM facilities. As an alternative, pharmaceutical sales representatives should be encouraged to offer voucher programs, which allow patients to get starter supplies of medications through organized distribution channels instead of pharmaceutical samples.

A. Definitions

Drug Samples: Prescription and non-prescription medications which are provided to the sites by pharmaceutical representatives for complimentary distribution to patients, as starter doses.

MSM/MMA Sites: Applicable to all MSM facilities where care is provided to patients.

Pharmaceutical Sales Representatives (PSR): A representative of a pharmaceutical manufacturer who visits the ambulatory care sites for the purpose of soliciting the use of, or providing information about, pharmaceutical products. Representatives who visit MSM facilities for the sole purpose of initiating or monitoring research studies are exempt from these guidelines.

B. Standards

1. Drug samples shall not be made available for use by inpatients.
2. Sample medications are not permitted in MSM facilities except as noted in paragraph 4 below. This includes both patient care and non-patient care areas.
3. Vouchers approved by the MMA Operations Committee ("the Committee") may be distributed by MSM ambulatory care sites in order for patients to receive complimentary starter medications from a pharmacy of their choice. The Committee will determine a formulary of MSM-preferred medications, which then may be available through vouchers. Only vouchers approved by the Committee are permitted to be used by MSM clinicians at MSM facilities.
4. Non-approved vouchers may not be distributed by PSRs to MSM ambulatory care sites, nor dispensed by MSM personnel at MSM sites.
5. Under special circumstances in which there is a legitimate clinical need, with the approval noted below, sample medications may be permitted in MSM facilities. Specific requests to have physical samples in a MSM clinic must be made on the Special Cause Sample Request Form, and be approved by the Committee and the MMA Associate Dean for Clinical Affairs.

6. Control of drug samples/vouchers shall be monitored jointly by the Clinical Compliance and Privacy Officer and the MMA Associate Dean for Clinical Affairs.

C. Procedure Actions

1. Participating pharmaceutical companies may distribute the Committee-approved vouchers to MSM/MMA clinics through their sales representatives. These vouchers are for generic medications or brand drugs that are designated as "preferred" by the Committee.
2. PSRs may not distribute non-approved vouchers or coupons within MSM sites, or to MSM clinicians.
3. If a clinic medical director believes there is a clinical need to maintain some physical samples, a request will be made to the Committee, the MMA Associate Dean for Clinical Affairs, and the Clinical Compliance and Privacy Officer using the Special Cause Sample Request Form. If the request is approved, the succeeding steps must be followed:
 - a. A formulary of approved sample products must be approved for the clinic and samples of only those products are permitted at the site.
 - b. The approved products must be reviewed annually by the Associate Dean for Clinical Affairs and the Clinical Compliance and Privacy Officer.
 - c. Samples must be stored in a locked secure area that prohibits unauthorized access or that is under constant supervision or surveillance. PSRs are not authorized to have access to drug sample storage areas.
 - d. Samples are properly stored under proper conditions of sanitation, temperature, light, moisture, ventilation, segregation, and safety, according to manufacturer's specifications and law and regulation.
 - e. When samples are received from the manufacturer, they must be recorded on the Sample Drug Log-in Form.
 - f. The sample drugs must be inspected by the Associate Dean for Clinical Affairs or designee monthly, and a copy of this review sent to the Clinical Compliance and Privacy Officer.
 - g. Samples are organized to allow for easy retrieval, yet segregated to prevent medication errors. Storage areas must be routinely inspected to check for expired and deteriorated sample medications; samples stored in the wrong place; drugs that can no longer be identified by name, strength, and expiration date; and other medications that do not belong in that area.
 - h. Samples for prescription drugs are labeled and dispensed according to the same standardized method that MSM uses for non-sample prescription medications.

- i. In the event of a drug recall, the Clinical Compliance and Privacy Officer will notify the clinic. The Associate Dean for Clinical Affairs or designee must review sample inventory and return recalled drugs to the pharmacy.
 - j. When dispensing a sample medication to a patient, the physician must select the drug, dose and quantity of medication to be dispensed. This must be recorded in the patient's medical record. The physician must review the dose-pack and patient label with written instructions prior to the medication being dispensed to the patient.
 - k. The physician may delegate to a medical assistant or nurse the following steps:
 - i. Complete the Sample Drug Sign-Out Log.
 - ii. Complete the Sample Medication Label.
 - iii. Document the patient waiver of a child-proof container
 - iv. Obtain final approval from the physician before dispensing
 - v. Provide patient education regarding the medication
4. The Clinical Compliance and Privacy Officer will inspect the sample medication storage, log, and dispensing process at least annually. If adherence to this policy is not being met, the privilege of maintaining samples will be revoked.

4. Site Access

MSM does not allow use of their facilities or other resources for marketing activities by Industry. MSM always reserves the right to refuse access to their facilities or to limit activities by Industry representatives consistent with their non-profit mission. However, interaction with representatives of Industry is appropriate as it relates to exchange of scientifically valid information and other data, interactions designed to enhance continuity of care for specific patients or patient populations, as well as training intended to advance healthcare and scientific investigation.

To balance these interests, MSM's Procurement Office will develop a registry to assist in the management of site access by Industry representatives for appropriate purposes. Sales or marketing representatives of Industry may access MSM facilities only if the company with which they are associated has registered with the MSM Procurement Office, and they have been specifically invited to meet with an individual healthcare provider or a group of healthcare providers for a particular purpose. Individual physicians or groups of physicians or other healthcare professionals may request a presentation by or other information from a particular company through the MSM Procurement Office or other designated institutional official.

Industry representatives should not be permitted in any patient care area unless ***each*** of the following exceptions is met:

- A. The representative is present to provide in-service training on devices and other equipment, including provision of essential guidance on the use of such equipment.
- B. The presence of the representative is expressly requested and approved in advance by a faculty member.

C. The device representative is certified by their employer to provide the requested device training.

Industry representatives should never provide direct patient care services at MSM.

Industry representatives are permitted in non-patient care areas by scheduled appointment only. Therefore, representatives should not be in any MSM facilities without a scheduled appointment with a faculty member or other authorized MSM personnel.

Industry representatives without an appointment as outlined above are not allowed to conduct business in patient care areas (inpatient or outpatient), in practitioners' office areas, or other areas of MSM clinical facilities.

All Industry personnel seeking sales or vendor relationships must work directly with the MSM Procurement Office. While in MSM facilities, all Industry representatives must be identified by name and current company affiliation in a manner determined by such department, as applicable.

All Industry representatives with access to MSM clinical facilities and personnel must comply with institutional requirements for training in ethical standards and organizational policies and procedures.

5. Support of Continuing Medical Education or Graduate Medical Education

Industry support of continuing medical education ("CME/GME") in the health sciences 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 potential for bias is minimized and that CME/GME programs are not a guise for marketing, all CME/GME events hosted or sponsored by MSM must comply with the ACCME Standards for Commercial Support of Educational Programs (or other similarly rigorous, applicable standards required by other health professions), whether or not CME/GME credit is awarded for attendance at the event.

All such agreements for Industry support of CME/GME programs must be negotiated through and executed by the Continuing Medical Education Department, and must comply with all policies for such agreements. Funding may be restricted to a clinical department and must be overseen by the Department Chair. Funding may not be restricted to a clinical division, a specific program or an individual physician. The CME Committee will oversee Industry sponsorship exceeding established thresholds (see below) to ensure potential conflicts of interest are appropriately managed.

Any such educational programs must be open on equal terms to all interested practitioners, and may not be limited to attendees selected by the company sponsor(s). Industry 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 for social events that do not have an educational component. Industry funding may not be accepted to support the costs of internal department meetings or retreats (either on- or off-campus).

Product Symposia by MSM exclusively for the education of MSM personnel, MMA patients or the broader community are permissible. Industry products directly related to a MSM

educational event may be displayed and discussed as part of the educational event. Industry funding to support these activities is acceptable provided it is processed consistent with this section.

Industry Product Fairs are prohibited. Industry representatives are never permitted to display or market any products on any MSM premises, unless they are directly related to a MSM sponsored education event, as noted above.

MSM facilities (clinical or non-clinical) may not be rented by or used for Industry funded and/or directed programs, unless there is a CME/GME agreement for Industry support that complies with the policies of the CME Committee. Dedicated marketing and training programs designed solely for sales or marketing personnel supported by Industry are prohibited.

The Office of Compliance and Internal Audit will review and oversee Industry sponsorship to assess potential conflicts of interest and to propose approaches for management of such potential or actual conflicts of interest. The Office of Compliance and Internal Audit and the Office of General Counsel will review any Industry contribution exceeding \$10,000 in support of CME/GME (fellowship or other support), or general research support in any one fiscal year.

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

MSM medical staff, faculty, staff, residents, interns, students, and trainees may participate in or attend Industry-sponsored meetings, or other off-campus meetings where Industry support is provided, so long as: (a) the activity is designed to promote evidence-based clinical care and/or advance scientific research; (b) the financial support of Industry is prominently disclosed; (c) if the MSM representative is an attendee, Industry does not pay attendees' travel and attendance expenses; (d) attendees do not receive gifts or other compensation for attendance; (e) meals provided are modest (i.e., the value of which is comparable to the Standard Meal Allowance as specified by the United States Internal Revenue Service) and consistent with the educational or scientific purpose of the event. MSM shall not market the event and MSM faculty shall not instruct or encourage participation in or attendance at the event. In addition, if a MSM representative is participating as a speaker: (a) all lecture content is determined by the MSM speaker and reflects a balanced assessment of the current science and treatment options, and the speaker makes clear that the views expressed are the views of the speaker and not MSM; (b) compensation is reasonable and limited to reimbursement of reasonable travel expenses and a modest honorarium not to exceed \$2,500 per event.

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

MSM may accept Industry support for scholarships or discretionary funds to support trainee or resident travel or non-research funding support, provided that all of the following conditions are met:

- a. Industry support for scholarships and fellowships must comply with all MSM requirements for such funds, including the execution of an approved budget and written gift agreement through the Office of Institutional Advancement, and be maintained in an appropriate restricted account, managed at the school or department as determined by the President, the Dean, or his/her designee. Selection of recipients of scholarships or fellowships will be

completely within the sole discretion of the school in which the student or trainee is enrolled or, in the case of graduate medical education, the associate dean for graduate medical education. Written documentation of the selection process will be maintained.

- b. Industry support for other trainee activities, including travel expenses or attendance fees at conferences, must be accompanied by an appropriate written agreement and may be accepted only into a common pool of discretionary funds, which shall be maintained under the direction of the dean or department (as specified in the funding agreement) for the relevant school. Industry may not earmark contributions to fund specific recipients or to support specific expenses. Departments or divisions may apply to use monies from this pool to pay for reasonable travel and tuition expenses for residents, students, or other trainees to attend conferences or training that have legitimate educational merit. Attendees must be selected by the department based upon merit and/or financial need, with documentation of the selection process provided with the request. Approval of particular requests shall be at the discretion of the dean.

8. Frequent Speaker Arrangements (Speakers Bureaus) and Ghostwriting

While one of the most common ways for MSM to disseminate new knowledge is through lectures, "speakers bureaus" sponsored by Industry may serve as little more than an extension of the marketing department of the companies that support the programming. Before committing to being a speaker at an Industry-sponsored event, careful consideration should be given to determine whether the event meets the criteria set forth in Section 6 of this policy, relating to Industry Sponsored Meetings.

MSM personnel may not participate in, or receive compensation for, talks given through a speakers bureau or similar frequent speaker arrangements if: (a) the events do not meet the criteria of Section 6; **or** (b) if the content of the lectures given is provided by Industry or is subject to **any** form of prior approval by either representatives of Industry or event planners contracted by Industry; **or** (c) the content of the presentation is not based on the best available scientific evidence; **or** (d) the company selects the individuals who may attend or provides any honorarium or gifts to the attendees.

Under no circumstances may MSM personnel be listed as co-authors on papers ghostwritten by Industry representatives. In addition, MSM personnel should always be responsible for the content of any papers or talks that they give, including the content of slides.

Speaking relationships with company or company event planners are subject to review and approval of the participant's administrator, department chair, or dean as delineated in Section 2, Consulting Relationships.

9. Other Industry Support for Research

MSM, through the Office for Sponsored Research Administration, have established policies and contract forms to permit Industry support of research in a manner consistent with the non-profit mission of MSM. True philanthropic gifts from Industry may be accepted through the Office of Institutional Advancement.

REPORTING AND ENFORCEMENT

MSM personnel shall report their outside relationships with Industry using the Industry Conflict of Interest Disclosure Form, available online at the Office of Compliance and Internal Audit web site; at least annually and more often as needed to disclose new relationships. Alleged violations of this policy within MSM shall be investigated by the Office of Compliance and Internal Audit. Suspected violations of this policy shall be referred to the individual's dean and department chair or administrative management, who shall determine what actions, if any, shall be taken. Violations of this policy by MSM employees may result in the following actions (singly or in any combination), depending upon the seriousness of the violation, whether the violation is a first or repeat offense, and whether the violator knowingly violated the policy or attempted to hide the violation:

1. Counseling of the individual involved;
2. Written reprimand, entered into the violator's employment or faculty record;
3. Banning the violator from any further outside engagements for a period of time;
4. Requiring that the violator return any monies received from the improper outside relationship;
5. Requiring the violator to complete additional training on conflict of interest;
6. Removing the violator from supervision of trainees or students;
7. Revoking the violator's MMA hospital privileges;
8. Fines;
9. Termination for cause.

Any disciplinary action taken hereunder shall follow the established procedures of MSM.

Industry representatives who violate this policy may be subject to penalties outlined in MSM Procurement Guidelines, or other applicable MSM policies, as well as other actions or sanctions imposed at the discretion of the President of MSM. Such penalties include the following:

Violation of any of the above procedures by representatives shall result in disciplinary action which may include, but shall not be limited to, the following:

1. First violation: Verbal and written warning to representative; written notification to district manager or representative's supervisor.
2. Second violation: Suspension of representative and all other company sales/marketing representatives from MSM for six months.
3. Third violation: Suspension of representative and all other sales and marketing representatives of the company from MSM for one year or more. A review of multi-source products obtained from the company will be conducted.

Representatives found trespassing as defined in this policy will be escorted from the premises and their companies notified as appropriate.