

■ Gifts and Meals

Background: Numerous published studies demonstrate that both small and large gifts play a role in influencing prescribing decisions, which directly affect patient care. Medical personnel consistently underestimate the extent to which they personally are influenced. Industry-sponsored meals are a form of gifting. A clear and complete ban not only removes all potential conflict of interest – perceived or real – it also removes the burden of compliance with a more nuanced policy.

Recommendation: All gifts and on-site meals funded by industry are prohibited, regardless of nature or value.

■ Consulting relationships with industry (excluding scientific research and speaking)

Background: There is a clear benefit to collaboration between academic physicians and industry in the interest of developing better products. However, it is not uncommon for consulting relationships to exist where payment exceeds, sometimes greatly, what would normally be thought appropriate for the services rendered. Such consulting relationships become de facto gifts.

Recommendation: Consulting relationships with industry must be subject to institutional review or approval. Additionally, they must be described in a formal contract where payment for services is commensurate to the task.

■ Industry-funded speaking relationships

Background: Research relationships with industry may entail beneficial public presentations and speeches by individual researchers. However, industry also uses academic physicians to support marketing goals by identifying and cultivating speakers who give a positive message about the drug in question. Such ongoing relationships, sometimes called “speakers bureaus,” are detrimental to evidence-based prescribing.

Recommendation: Speaking relationships are prevented from functioning as de facto gifts or marketing. An effective policy must not implicitly permit (a) long-term speaking agreements or (b) industry to have a role in determining presentation content. (Elements of effective policies include, for example: explicitly prohibiting participation in speakers bureaus; limiting compensation and reimbursement for speaking engagements; and a requirement to ensure the scientific integrity of information presented.)

■ Disclosure

Background: Disclosing relationships with industry identifies and allows management of conflicts where they do exist; this practice also helps remove the question of conflicts where they do not exist. For these reasons, disclosures should be required of all faculty and staff, even if there is no financial relationship. In this way, concerns of underreporting or overreporting will be alleviated. Public disclosure should ideally be always in place, but disclosure to patients is particularly important where conflicts may insert real or perceived bias into treatment decisions, and may affect quality of care. Faculty disclosures should also be made during lectures and other educational presentations.

Recommendation: All personnel are required to disclose past and present financial ties with industry (e.g., consulting and speaking agreements, research grants), ideally on a publicly-available website and/or disclose such relationships to patients when such a relationship might represent an apparent conflict of interest.

■ Pharmaceutical Samples

Background: The U.S. pharmaceutical industry distributes some \$18 billion per year in drug samples. Published studies show that a substantial proportion of these samples are used by physicians, staff and their families. Such use is a clear financial conflict of interest that confers no possible benefit on patients.

When sample medications are accepted and dispensed in the clinic setting, the usual standards of inventory control, drug interaction and dosage screening, labeling and documentation may be bypassed (contravening Joint Commission standards for hospital accreditation). Distribution of non-formulary drug samples has the potential to undermine the intent and function of the formulary.

Furthermore, the distribution of samples has been shown to lead physicians to prescribe drugs that differ from their preferred drug choice, reducing their prescribing of unadvertised drugs in favor of advertised drugs and decreasing their use of first-line (relative to second-line) therapies. This suggests that the direct distribution of samples to physicians, in aggregate, increases costs while reducing the safety and effectiveness of prescribing.

Recommendation: Industry samples are prohibited, except under certain narrow circumstances approved by the institution that protect the interests of patients and prevent the use of samples as a marketing tool (e.g., policies that allow samples under limited circumstances with the approval of the Pharmacy and Therapeutics (P&T) Committee or policies that incorporate samples into a larger program designed to ensure the availability of brand-name and generic medications to under-insured patients; if the circumstances of the specific program are not defined, the policy should define the approvals process). Where there is a specific program in place, the policy must prevent samples from being given directly to physicians by pharmaceutical sales representatives.

■ Purchasing & Formularies

Background: Individuals with financial conflicts of interest should not make institutional purchasing decisions. Decisions influenced by personal conflicts have the potential to adversely affect institutional costs and the quality of patient care.

Pharmacy and Therapeutics (P&T) Committees typically decide which drugs will be on the hospital's "preferred list," known as a formulary. Other committees may make other purchasing decisions.

Recommendation: Formulary committees and committees overseeing purchases of medical devices should exclude those who have financial relationships with drug or device manufacturers. Exclusion may be specific to participation in particular decisions for which the staff member has a conflict of interest. This policy does not prevent expert clinicians from advising a committee, provided that potential conflicts are disclosed. (Note: this standard is not intended to prohibit indirect financial interests, such as investments in mutual funds that may own pharmaceutical company shares).

■ Site Access

Background: Industry sales representatives are employed to increase the sales of their companies' drugs. They present doctors with research and other information that is carefully chosen to demonstrate the benefits of the drugs that they are marketing, not to be representative of the literature on those drugs. Ultimately, doctors should not be relying on advertisements when making prescribing decisions. Permitting industry representative access to medical staff is not in the interests of patients or staff. Published, peer-reviewed medical evidence is summarized for physicians by several organizations that do not have conflicts of interest. Such sources include: The Cochrane Library, Drug and Therapeutics Bulletin, Drug Effectiveness Review Project (the findings of which are further summarized for patients by Consumer Reports Best Buy Drugs), First Consult, The Medical Letter, National Institute for Health and Clinical Excellence (United Kingdom), Prescribe International, and Therapeutics Initiative.

Recommendation: Pharmaceutical and device representatives are not allowed to market their products anywhere inside the medical center and associated clinics and offices. (Exceptions may be made for non-marketing purposes, such as training on devices or equipment, when at the request of physicians who have purchased such equipment)

■ Education

Background: It is essential that financial support not influence the content of educational activities. Where financial support from industry assists in the delivery of educational activities, it must not be linked to an individual company's interest in promoting specific products. Industry influence on CME content has been extensively documented. Allowing the pharmaceutical industry to play such a role in physician education compromises clinical care and medical professionalism. Therefore, a firewall should separate the donor from those developing the educational activity. Educational activities take place both "on-site" (that is, within the medical school or hospital campus) and "off-site" (at outside facilities, including professional conferences). Many policies distinguish between on-site and off-site activities.

Recommendation: On-site Educational Activities: Industry is not permitted to provide direct financial support for educational activities, including Continuing Medical Education (CME), directly or through a subsidiary agency. (However, companies may contribute unrestricted funds to a central fund or oversight body at the academic medical center, which, in turn, would pool and disburse funds for programs that are independent of any industry input or control.)

Recommendation: Compensation for Travel or Attendance at Off-site Lectures & Meetings: Personnel may not accept payment, gifts or financial support from industry to attend lectures and meetings. (An exception may be made for modest meals, if part of a larger program)

Recommendation: Industry Support for Scholarships & Funds for Trainees: The policy must either prevent industry from earmarking or awarding funds to support the training of particular individuals (recipients must be chosen by the school or department), or the policy must mandate institutional review of the giving of funds. (This does not preclude grants that fund a specific research project.)

Recommendation: Medical school curriculum: Students and residents are trained to understand institutional conflict-of-interest policies and recognize how industry promotion can influence clinical judgment.

■ Enforcement

Recommendation: An established party is responsible for oversight, and there are clear sanctions for noncompliance.