Policy on Conflicts of Interest in Clinical Care

Pharmaceutical and Medical Device Industry Policy - Interaction with Industry Representatives

Approved by FPP Board of Directors: May 22, 2007

Purpose

Pharmaceutical and medical device representatives have an interest in making health care professionals aware of their products and new product developments. While interactions with sales representatives have a legitimate purpose, it is essential that information provided by these individuals is free of bias and financial inducements that might unduly influence medical decision making. The purpose of this policy is to define ethical standards for interacting with pharmaceutical and medical device manufacturers.

Definition

For purposes of this Policy, "medical device" is defined broadly to include medical devices, implants and other medical care related products and services.

Policy

1) Vendor sales representatives are allowed on WUSM premises, including its off-site clinics, only by appointment and only in department-designated areas as approved by the Department Chair, Program Director or their respective designees. Vendor sales representatives must wear visible identification while on any WUSM premises, and the purpose of their visits must be educational, not promotional, in nature.

2) Vendor sales representatives are prohibited from having direct patient contact and are not permitted to meet with faculty in patient care areas. Any exceptions to this policy must be approved by the Department Chair or Program Director and limited to situations in which the presence of a medical device representative is essential because of the complexity of the medical device being utilized.
3) Pharmaceutical/medical device manufacturers may only provide unrestricted educational grants to a central fund with the approval of the Department Chair, Program Director or the representative designees. The fund is independent of any industry input or control.

- Grants may be used for medical education purposes including, but not limited to, medical textbooks, honoraria and expenses for extramural lecturers and the provision of modest food/meals.

- Grants cannot be conditional or related in any way to any pre-existing or future business relationship with the industrial sponsor.

- The content of the educational program and related materials must be under the exclusive control of WUSM.

- Financial support of programs can be acknowledged in text in program announcements (Ex: “This program was supported in part by an educational grant from _____.”)

4) When industry provides support of CME-accredited educational activities, additional CME guidelines and procedures for commercial support of educational activities must be followed. Up-to-date versions of these standards can be found at the CME web site (http://cme.wustl.edu). University resources including campus mail, e-mail or other official means of communication should not be used to announce or publicize industry-sponsored or co-sponsored events:

- Educational events may be publicized if supported by an unrestricted educational grant.

- Pharmaceutical/medical device manufacturers should not be provided with e-mail lists or address lists of WUSM physicians, health professionals, students, trainees, residents or staff.

5) Vendor sales representatives may not interact with students, residents and other trainees on WUMC premises without faculty presence. Vendors may provide only peer-reviewed literature and technical information related to the use of medical devices in this setting. With approval from the appropriate Department Chairperson or Program Director vendors may provide medical textbooks to students, residents and other trainees. Departmental or Program review and approval will include the educational materials as well as the distribution process.

6) Promotional items (pens, notepads, magnets, etc.) are not allowed in clinical practice areas or at educational conferences for students, residents and other trainees.

7) Industry-sponsored food and catered meals are not permitted in any WUSM area (clinical or academic) and are not permitted at educational conferences for students, residents and other trainees unless provided through an unrestricted departmental grant.

8) Pharmaceutical samples from industry are prohibited, except under narrow circumstances approved by the Faculty Practice Plan Clinical Practice Committee that protect the interests of patients and prevent the use of samples as a marketing tool. Permitted uses are limited to:
• Low-income uninsured or underinsured patients who are unable to afford prescriptions.

• Situations in which the patient’s response to sample medications can be helpful in determining the most effective treatment before writing a full prescription.

• The medications must only be accepted by the clinic site manager and stored in a secured location. A log must be maintained to document their use, including the date, patient’s name, medication name, lot number, expiration date, indication for use and quantity dispensed. Sample medications may not be given directly to physicians by pharmaceutical sales representatives.

9) Meals, sporting event tickets, golf outings, gift baskets, travel, and any other free goods or services should not be accepted from vendors.

10) Faculty and staff members (including their spouses, domestic partner or dependent children) who receive payments from a pharmaceutical or medical device manufacturer or distributor, or who have a personal financial interest in such companies, must not make decisions regarding WUSM and affiliated hospital purchases related to the products of such companies.

To the extent an individual’s expertise is necessary in evaluating any product, the individual must report his or her financial or fiduciary ties (or those of his/her spouse, domestic partner or dependent child) to any manufacturer of the product to those responsible for making the procurement decision. The individual may provide information, but may not participate in the final purchasing decisions relevant to such products.