

PHARMACEUTICAL AND DEVICE INDUSTRY AND CONFLICT OF INTEREST POLICY



The primary goal of this policy is to create a learning environment at the Alpert Medical School (AMS) that will promote the practice of evidence-based, conflict-free medicine. Pharmaceuticals and medical devices are vital to the public health. In this regard, the pharmaceutical and device industries play a vital role in public health and medical care. At the same time, the industry has a primary fiduciary responsibility to deliver profits to its shareholders. The conflict between these financial interests and the ideals of medicine—altruism, service, and protection of patients—require close evaluation by the medical profession and its institutions of learning.

The trust placed in the medical profession by the public is subject to the perception that physicians are unduly influenced by the pharmaceutical and device industries. The pharmaceutical industry alone spends \$25 billion each year in direct marketing to physicians, including detailing by drug reps, journal ads, samples, and gifts¹ with the ultimate goal of changing prescribing behavior. Studies have shown that even small gifts influence prescribing behavior,² and that marketing leads to increased formulary requests³ and decreased use of generic medications.⁴

BACKGROUND AND RECOMMENDATIONS

Gifts

Industry uses gifts because they work to increase sales of their products – gifts have been shown to reduce generic prescribing, increase overall prescription rates, quicken uptake of new and expensive drugs over generics, increased formulary requests for new

¹ Donohue JM, Cevasco M, Rosenthal MB. A decade of direct-to-consumer advertising of prescription drugs. *N Engl J Med.* 2007;357:673-681.

² Dana J, Loewenstein G. A social science perspective on gifts to the industry. *JAMA.* 2003;290:252-255.

³ Wazana A. Physicians and the pharmaceutical industry: Is a gift ever just a gift? *JAMA.* 2000;283:373-380.

⁴ Chren MM, Landefeld CS. Physicians' behavior and their interactions with drug companies. A controlled study of physicians who requested additions to a hospital drug formulary. *JAMA.* 2007;297:1216-1223.

drugs.⁵ Gifts create real and perceived conflicts of interest, which patients regard as inappropriate.⁶ Ninety-four percent of physicians accept some type of gift,⁷ yet the majority underestimate the extent to which they are influenced by these gifts.^{8,9}

Gifting often begins in medical school and continues throughout a physician's life. Studies on medical students and residents show a comparable amount of interaction as with practicing physicians and industry. Over ninety percent of students and residents report accepting a non-academic gift from an industry representative or attending an industry meal. However, over two-thirds of medical students believe that these gifts have no bearing on their future prescribing patterns. They view their peers as easier targets; forty-two percent of students believe that their fellow physicians are affected by such gifts.¹⁰

Policy: Students may not accept any form of personal gift from industry or any of its representatives, regardless of nature or dollar value. Students may not accept promotional materials such as pens, notepads, clocks, etc. from industry or any of its representatives. Such gifts may not be given to a larger body, such as a department, for distribution to students. Any academic materials such as books or equipment must be donated directly to the AMS administration and then distributed by the school itself with no input from industry.

Students may not attend any meals directly funded by industry, on or off-campus, or accept complimentary tickets to sporting or other events or any other hospitality from industry. Only Accreditation Council for Continuing Medical Education ("ACCME") accredited events should be attended. The medical school's office for Continuing Medical Education (CME) and the Dean for Medical Education should ensure that support of educational programs for trainees by industry is free of any actual or perceived conflict of interest.

⁵ Wazana A. Physicians and the pharmaceutical industry: Is a gift ever just a gift? *JAMA*. 2000;283:373-380.

⁶ Gibbons, RV, et al. A Comparison of Physicians' and Patients' Attitudes Toward Pharmaceutical Industry Gifts. *Journal of General Internal Medicine*. March 1998. 13;3: 151-154.

⁷ Campbell EG, Gruen RL, Mountford J, Miller LG, Cleary PD, Blumenthal D. A national survey of physician-industry relationships. *N Engl J Med*. 2007;356:1742-1750.

⁸ Chren MM. Interactions between physicians and drug company representatives. *Am J Med*. 1999;107:182-3.

⁹ Chimonas S, Brennan TA, Rothman DJ. Physicians and drug representatives: Exploring the dynamics of the relationship. *J Gen Intern Med*. 2007;22:184-190.

¹⁰ Sierles F, et al., "Medical Students' Exposure to and Attitudes About Drug Company Interactions: A National Survey," *JAMA* 2005;294:1034-1042.

Students may not accept any compensation from industry for services, attendance at CME or instructional activities, or for travel expenses. Students may, on their own time, accept employment or an internship at an industry company, including the appropriate market-based compensation included in this employment. Any funding from industry for travel must be donated directly to the AMS administration and then distributed by the school itself with no input from industry.

This policy applies to students in all clinical and research settings, including clinical clerkships and Doctoring mentor sites.

Site Access by Industry Representatives

Pharmaceutical and medical device industry sales representatives (vendors) have often had relatively unrestricted access to large academic medical centers (AMCs), community hospitals, and physicians' offices.¹¹ The pharmaceutical industry employs about 100,000 sales representatives amounting to one pharmaceutical representative for every eight physicians.¹² Sales representatives frequently do not provide complete and accurate information regarding the efficacy of their products.¹³ Policies limiting the number and nature of interactions between resident physicians and industry representatives lead them to become more skeptical about industry-provided information.¹⁴

Policy: AMS strictly limits the amount of student-industry interaction in order to remove any potential conflicts of interest from medical education and patient care. Specifically, industry representatives will not be allowed on the AMS campus or inside classrooms. Industry representatives will be restricted from direct contact with students, on or off the AMS campus. In addition, no attempts at contact, such as e-mailing or calling students, will be permitted.

In the case of an unavoidable interaction with industry representatives, a faculty physician must be present for all interactions. As stated in the section on gifts, students should not accept any gifts (regardless of value), including meals or free samples from

¹¹ Elliott, C. "The Drug Pushers" Atlantic Monthly April 2006.

<http://www.theatlantic.com/doc/200604/drug-reps>

¹² Wazana, A. Is a gift ever just a gift? JAMA. 2000;283:373-380.

¹³ Molloy W, Strang D, Guyatt G, et al. Assessing the quality of drug detailing. *J Clin Epidemiol.* 2002;55:825-832

¹⁴ McCormick, B., et al., "Effect of Restricting Contact Between Pharmaceutical Company Representatives and Internal Medicine Residents on Posttraining Attitudes and Behavior," *JAMA: The Journal of the American Medical Association* 286, no. 16 (2001): 1994-1999.

the industry representative. Interactions between students and representatives should also be allowed in limited circumstances when the expertise of the representative is required for instruction in the use of a device and a physician is present to supervise the interaction. Under these circumstances, representatives are required to identify themselves in order to distinguish themselves from clinical staff. At all times, we encourage students to seek out evidence-based unbiased sources of information about drugs and devices.

Note on Doctoring Community Mentor Sites: We recognize that enforcing a student policy on industry interaction is particularly challenging at Doctoring Community Mentor sites, which are dispersed throughout Rhode Island and surrounding Massachusetts. Each hospital or practice to which the student is assigned may have a different policy. To ensure consistency in student training, mentors are instructed to minimize, if not eliminate, student contact with industry representatives during their community mentor sessions.

Industry Sponsored Scholarships

Partnerships between academic centers and industry are commonplace. Studies have shown that at least ninety percent of companies conducting life-science research in the United States had research relationships with an academic institution.¹⁵ Institutional administration and oversight of scholarships and other educational funds help to prevent the establishment of one-on-one relationships between industry and students. At the same time, it is vital that students have access to opportunities for educational or research funding, and AMS should be committed to providing such access.

Policy: If a student wishes to apply for or accept educational or research funding directly from industry, they may do so if and only if the funds are unrestricted (meaning no quid pro quo agreements are made).

All other scholarships or other educational funds must be given centrally to the AMS administration, and should be unrestricted. The evaluation and selection of recipients of such funds should be the sole responsibility of the AMS administration with no input from industry.

¹⁵ Blumenthal D. "Relationships between academic institutions and industry in the life sciences--an industry survey." *New England Journal of Medicine*. 1996 Feb 8;334(6):368-73.

ADDITIONAL MEASURES

- All lecturers in the preclinical curriculum (years MD1 and MD2) must open their Powerpoint presentations with a “disclosure” slide. Guidelines for these disclosures will follow standard CME practice.
- Lectures given during the clinical years (MD3 and MD4) must begin with a disclosure of conflicts of interest. Clerkship directors and faculty supervisors for other clinical rotations will assure that students are provided with information about the sponsors of all conferences. Students will not be required to attend conferences directly sponsored by industry.
- Content on the impact of industry, direct marketing to patients and other related issues is incorporated into the preclinical and clinical curricula.
- Applications for summer assistantships (summer between years MD1 and MD2) include a COI form that must be completed by the student’s designated mentor. Applications will not be considered without a completed form.
- Applications for non-clinical independent studies (research or service activities) are accompanied by the same form. Students will not be registered for independent studies without a completed form.

MONITORING AND COMPLIANCE

Students who violate the above policies will be subject to disciplinary action via the same processes applied to other violations of the academic and non-academic codes. Monitoring for compliance, dealing with individual cases, and yearly re-evaluation of the policies will be the responsibility of the Associate Dean for Medical Education in consultation with the appropriate administrators, clerkship directors, and the Medical Student Senate.

The above policies are intended to optimize the AMS learning environment. The complexity of the AMS system, which includes affiliated hospitals, foundations, health centers and community physicians, dictates that these policies be monitored and modified to assure their effectiveness. Issues regarding the implementation of this policy should be directed to the Associate Dean for Medical Education.