THE PRESCRIPTION PROJECT

September 12, 2007

Time for Change

The Prescription Project promotes evidence-based prescribing and works to eliminate conflicts of interest in medicine due to pharmaceutical marketing to physicians.

It is promoting policy change by working with

- *State and Federal Policymakers*
- *Academic Medical Centers*
- *Professional Medical Societies*
- *Private Payers*

Created with The Pew Charitable Trusts, the Project is led by Community Catalyst in partnership with the Institute on Medicine as a Profession.

Addressing Conflicts of Interest at Academic Medical Centers

Introduction

Academic medical centers (AMCs) form the intellectual core of medicine, training future doctors and researchers, and establishing standards that guide practicing physicians in the wider community. Where pharmaceutical industry marketing conflicts with the goals of patient care and professionalism, AMCs can provide leadership and guidance by establishing new standards on physician-industry relationships.

I. The Problem

The pharmaceutical industry spends more than $25 billion each year in direct marketing to physicians, including more than $7 billion for detailing and journal advertising and $18 billion for samples.[1] Ninety thousand sales representatives are deployed.[2] Many promote new and expensive products that lack clear therapeutic advantage and may have unknown adverse effects.[3] Industry representatives often gain access to doctors by offering meals, drug samples and other gifts. This intense marketing is widely believed to undermine quality of care and increase costs to patients, public programs, health care institutions, health insurers and employers.[4-6]

Gifts generate conflicts of interest. Physicians who accept company gifts may feel a need, subconscious or otherwise, to reciprocate.[7] Even small gifts change behavior;[7] public records show that many clinicians receive tens of thousands of dollars per year from the industry.[8]

Industry sales representatives frequently provide inaccurate information (reviewed in Molloy et al.).[9] Yet contact with sales representatives or acceptance of industry support leads to increased prescribing of the funders' products, increased requests for formulary inclusion and decreased use of generic medications.[3, 10] Nearly all physicians (more than 90 percent) have some relationship with industry,[11] but many often fail to realize the extent to which these relationships influence their own prescribing decisions.[12-14]

Relationships between medicine and industry also exist at the institutional level. Many AMCs depend heavily on pharmaceutical company support for research, education and other organizational activities.[15] Positive relationships with industry may confer institutional benefits, but the attendant conflicts of interest must be addressed.

II. Setting new standards

In January 2006, a group of leading physicians and researchers from the Institute of Medicine as a Profession (IMAP) and the American Board of Internal Medicine Foundation called for AMCs to take the lead in ending conflicts of interest between physicians and pharmaceutical companies. Writing in the *Journal of the American Medical Association* (*JAMA*), the authors outlined several recommendations toward change.[16] The article generated a great deal of interest in the press and from within the medical profession.[17-22] Following its publication, a number of AMCs strengthened their policies. The Prescription Project was launched by The Pew Charitable Trusts in February 2007 with a major goal of promoting the *JAMA* recommendations.

To assess current conflict of interest policies at—and recommend "best practices" for— AMCs, the Prescription Project conducted an in-depth investigation of policies, or draft policies, at a number of leading AMCs. Using online research and interviews, we collected information on policies as well as implementation histories, successes, failures, and future plans. Drawing on the *JAMA* recommendations, we used the following specific criteria for assessing policies:

1. **Gifting**: Do AMCs permit gifts to physicians from industry? Are there any restrictions on "giveaway" items, meals, payment for travel to, or time at, meetings, or payment for CME participation?

2. **Drug samples**: Do AMCs permit physicians to accept samples? Or is there a system (e.g. vouchers for low-income patients) that distances the company from the physician? Are samples limited to patient use, or may physicians use samples for themselves and their families?

3. **Drug formularies**: Do AMCs permit physicians with financial ties to drug companies to serve on committees overseeing formularies or the purchase of medical devices?

4. **Continuing medical education (CME)**: How do AMCs manage industry funds for CME? What policies are in place to ensure that CME events remain free of influence from donors?

5. **Funds for physician travel**: Do AMCs permit manufacturers to directly fund travel of faculty and trainees? What policies govern funds for physician travel?

6. **Speakers bureaus and ghostwriting**: Do AMCs allow faculty to serve on speakers bureaus or to publish articles or editorials that are ghostwritten by companies?

7. **Consulting and research grants**: How do AMCs oversee grants for consulting and research? Do they require an explicit contract with specific deliverables? Do they allow "no strings attached" grants and gifts to individual researchers?

III. Progress toward best practices

In the 18 months since the publication of the *JAMA* recommendations, more than a dozen AMCs around the country have responded to the call to adopt more stringent regulations.

The Prescription Project has been actively engaged with leaders at AMCs, including the University of California, Los Angeles and the University of Massachusetts, as well as the institutions mentioned in Table 1. We have assisted a number of these centers in drafting and implementing new policies. We are also working with select AMCs to conduct in-depth case studies that will provide new insights for institutions and leaders nationally.

Following are "best policies" in each of the issue areas addressed in the *JAMA* recommendations. Leaders at other AMCs can use these exemplary policies to begin discussions with faculty and staff about the importance and feasibility of strengthening existing regulations. Doing so will improve patient care and protect the integrity of medical decision-making by reducing the influence of industry marketing on prescribing patterns.

Table 1: Examples of model policies

Issue Area	Academic Medical Center	Exemplary Policy
Gifts	Kaiser Permanente, Veterans Affairs	Physicians may not accept any form of personal gift from industry or its representatives.
Meals	University of Wisconsin, University of Pittsburgh	Food or drink may not be provided by any vendor.
Samples	University of Michigan	Sample medications are not permitted in University of Michigan Hospitals and Health Centers (UMHHC), including both patient and non-patient areas. Under special circumstances, in which there is a legitimate clinical need, with the approval noted below, sample medications may be permitted in UMHHC. Specific requests to have physical samples in UMHHC clinics must be made on the Special Cause sample request form, and be approved by the Ambulatory Formulary Committee and the site medical director.
Pharmaceutical representative access to physicians	University of Pennsylvania, Boston University School of Medicine/Boston Medical Center	Pharmaceutical representatives are forbidden from patient areas. University of Pennsylvania's policies are very detailed, requiring representatives to register and schedule appointments to see physicians in their offices. BUSM/BMC does not permit interns, residents and other trainees to meet with sales representatives.

Issue Area	Academic Medical Center	Exemplary Policy
Formularies	Yale University	Yale Medical Group physicians who are involved in institutional decisions concerning the purchase of or approval of medications or equipment, or the negotiation of other contractual relationships with industry, must not have any financial interest (e.g., equity ownership, compensated positions on advisory boards, a paid consultancy or other forms of compensated relationship) in pharmaceutical companies that might benefit from the institutional decision. Indirect ownership through mutual funds is acceptable.
Continuing Medical Education	University of California at Davis	Industry support for continuing medical education goes into a central repository, and not directly (or indirectly, through a subsidiary agency) to an Accreditation Council for Continuing Medical Education (ACCME)-accredited program.
Scholarships and Fellowships	Stanford University	Industry-supported scholarships go directly to the department or division, and not to the individual. The department or division is required to verify the educational merits of the conference or program for which the student receives funding.
Consulting and Honoraria	University of Washington	University of Washington staff, like other state employees, may not receive honoraria, unless specifically authorized by the agency where they serve. An employee may not receive anything of economic value under any contract or grant outside of his or her official duties.

IV. External threats… and internal barriers

Public pressure for controlling conflicts of interest is growing. The national press reports regularly on the dangers and cost to patients of drug industry influence on physician decisions. Some states, including Vermont, Minnesota and Maine, have already passed laws limiting gifts to physicians or requiring public disclosure, while several Attorneys General have initiated or joined cases against potentially illegal relationships between pharmaceutical companies and physicians.[23-25] Washington, D.C. lawmakers are also considering action. Congressman Peter DeFazio (D-Ore) has introduced a bill requiring drug and device companies to disclose marketing and promotional gifts given to doctors.[26] Senator Chuck Grassley (R-IA) has introduced a similar measure,[27] and the Senate Finance Committee has begun investigating the extent of pharmaceutical industry influence over continuing medical education content.[28, 29] The Senate Aging Committee is also examining the influence of pharmaceutical industry marketing on medicine.[30]

Although some AMCs have begun to address these issues, the national landscape remains relatively unchanged. Through our discussions with AMC leaders, we have identified a number of barriers to moving ahead, and are developing strategies to counter them:

Barriers to Change	Strategies to Promote Improvement
Institutional dependency on drug industry funding for core functions, such as research, as well as ancillary support.	Organizations need to identify the extent of the support and how to compensate for its loss. For example, the University of Michigan has implemented programs for medical residents to ease the transition away from an estimated $2 million in industry-sponsored meals.
Ignorance of what other AMCs are doing about conflict of interest. Even organizations with more stringent policies were sometimes unaware of potential resources.	The Prescription Project is facilitating communication between institutions and serves as an information resource for AMCs.
Decentralized hospital/educational structure. A complex organizational structure complicates the process of policy change.	The Prescription Project is creating toolkits to provide AMCs in this position with concrete examples of how other institutions have overcome this challenge.
Fear of faculty resistance. Many institutions worry that eliminating gifts will anger faculty or prompt them to leave.	Our preliminary investigations have shown that appealing to the faculty's sense of responsibility as members of a prestigious institution can motivate faculty members to demonstrate professionalism and leadership by giving up industry perks. The Prescription Project also provides resources to educate the profession on the effects of industry marketing.
Over-reliance on disclosure. Institutions without firm policies may contend that disclosure is a sufficient response.	Disclosure eliminates neither conflicts of interest, nor their negative consequences.
Inadequate implementation. Some may believe it is impossible to police faculty behavior; that forbidden activities will simply move off-campus; or that AMC policies do not matter because most physicians work at multiple clinical sites.	Cultural change will not occur unless policies are accompanied by a commitment to implementation. Our work with AMCs suggests that formal policing may not be as crucial as educational initiatives. The Prescription Project is creating program guides and training to promote change.

As more AMCs strengthen their guidelines, some of these barriers will disappear. Industry threats to withdraw funding from stringent AMCs will lose effectiveness, and fears of competition for faculty will weaken.

V. Call to Action: Two Parts

Overcoming barriers and creating momentum for change requires leaders in the profession to think differently about conflict of interest. If the medical profession does not act, it will lose its prerogative.

We urge the Association of American Medical Colleges (AAMC) to provide leadership on these issues across all medical schools and teaching hospitals in the United States. The AAMC has convened a task force dedicated to this issue. To fulfill the AAMC mission of "strengthening the quality of medical education and improving the nation's health by enhancing the effectiveness of academic medicine," the organization must now promote a national agenda and a level playing field.

The AAMC should:

- Exert leadership by strengthening its guidelines related to conflict of interest
- Provide assistance to member AMCs so they can implement effective reforms
- Create an oversight committee to evaluate the actions of member organizations.

While the AAMC needs to provide overall guidance, it will be individual AMCs that determine the ultimate success or failure of efforts to eliminate conflicts of interest. Therefore, **we call on *all* academic medical centers to:**

- **Examine** best practices at other institutions, including those mentioned
- **Assess** current policies on conflict of interest
- **Engage** faculty broadly to build commitment at all levels
- **Address** key issues and announce the new policies to the professional and broader communities
- **Enforce** adherence through an effective monitoring system.

Conclusion

The medical profession and the public look to AMCs for leadership. New standards must demonstrate the importance of evidence-based practice, free from industry influence and bias. The Prescription Project is assisting AMCs by facilitating communication, providing toolkits and developing concrete and effective best-practice recommendations.

Strong standards will advance patient well-being and free physicians from conflicts of interest. Now is the time for action.

The Prescription Project (RxP), led by Community Catalyst and the Institute on Medicine as a Profession and funded by The Pew Charitable Trusts, seeks to eliminate conflicts of interest created by industry marketing by promoting policy change among academic medical centers, professional medical societies and public and private payers. The Prescription Project has spent the past six months working closely with academic medical centers to investigate their current polices and promote best practices among them.

REFERENCES

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. Sales makeover. *Medical Marketing & Media*. Nov, 2003.

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

4. Kassirer JP. *On the Take : How Medicine's Complicity with Big Business can Endanger Your Health.* New York: Oxford University Press; 2004.

5. Angell M. *The Truth about the Drug Companies: How they deceive us and what to do about it.* New York: Random House, Inc.; 2004.

6. Avorn J. *Powerful Medicines: The Benefits, Risks, and Costs of Prescription Drugs.* New York: Knopf; 2004.

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

8. Ross JS, Lackner JE, Lurie P, Gross CP, Wolfe S, Krumholz HM. Pharmaceutical company payments to physicians: Early experiences with disclosure laws in Vermont and Minnesota. *JAMA*. 2007;297:1216-1223.

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

10. 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*. 1994;271:684-689.

11. 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.

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

13. Madhavan S, Amonkar MM, Elliott D, Burke K, Gore P. The gift relationship between pharmaceutical companies and physicians: An exploratory survey of physicians. *J Clin Pharm Ther*. 1997;22:207-215.

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

15. Coyle SL. Physician-industry relations, Part 1: Individual physicians. *Ann Intern Med*. 2002;136:396-402.

16. Brennan TA, Rothman DJ, Blank L, et al. Health industry practices that create conflicts of interest: A policy proposal for academic medical centers. *JAMA*. 2006;295:429-433.

17. Harris G. In article, doctors back ban on gifts from drug makers. *New York Times*. Jan 25 2006;A14.

18. Girion L. Medical ethics reform urged: Ties between doctors and vendors undermine scientific integrity and patient care, group says. *Los Angeles Times*. Jan 26 2006.

19. Rubin R. Med schools urged to keep tabs on drugmakers. *USA Today*. Jan 24 2006.

20. Connolly C. Distance sought between doctors and drug industry. *Washington Post*. Jan 25 2007;A8.

21. Wilde Matthews A. Limits are sought for doctors ties to drug makers. *Wall Street Journal*. Jan 25 2006.

22. Kowalczyk L. New curbs urged on doctor perks: Small gifts seen influential. *Boston Globe*. Jan 25 2006.

23. Luke R. Utah AG makes Zyprexa eight in latest big pharma lawsuit pile-on. *LegalNewsline.com*. May 18 2007. Available from: http://www.legalnewsline.com/news/195364-utah-ag-makes-zyprexa-eight-in-latest-big-pharma-lawsuit-pile-on.

24. Department of Justice. Warner Lambert to pay $430 million to resolve criminal & civil health care liability relating to off-label promotion. Available at: http://www.usdoj.gov/opa/pr/2004/May/04_civ_322.htm. Accessed July 25, 2007.

25. Studdert DM, Mello MM, Brennan TA. Financial conflicts of interest in physicians' relationships with the pharmaceutical industry -- self-regulation in the shadow of federal prosecution. *N Engl J Med*. 2004;351:1891-1900.

26. House democrats' proposal takes aim at drug, device company gifts to doctors. *BNA Health Care Daily*. July 17 2007.

27. S.2029 "The Physician Payments Sunshine Act." www.govtrack.us/congress/bill.xpd?bill=s110-2029 Accessed September 12, 2007.

28. Committee on Finance United States Senate. Use of educational grants by pharmaceutical manufacturers. Available at: http://www.finance.senate.gov/press/Bpress/2007press/prb042507a.pdf. Accessed July 27, 2007.

29. Baucus M, Grassley C. Letter to Murray Kopelow, chief executive, Accreditation Council for Continuing Medical Education (Apr 25, 2007).

30. United States Senate Special Committee on Aging. Paid to prescribe? Examining the relationship between doctors and the drug industry

(hearing), June 27, 2007.