

Health Industry Practices That Create Conflicts of Interest

A Policy Proposal for Academic Medical Centers

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THE CURRENT INFLUENCE OF market incentives in the United States is posing extraordinary challenges to the principles of medical professionalism. Physicians' commitment to altruism, putting the interests of the patients first, scientific integrity, and an absence of bias in medical decision making now regularly come up against financial conflicts of interest. Arguably, the most challenging and extensive of these conflicts emanate from relationships between physicians and pharmaceutical companies and medical device manufacturers.¹

As part of the health care industry, pharmaceutical and medical device manufacturers promote the welfare of patients through their commitment to research and product development. Their investments in discovering, developing, and distributing new pharmaceutical agents and medical devices have benefited countless patients.

Conflicts of interest between physicians' commitment to patient care and the desire of pharmaceutical companies and their representatives to sell their products pose challenges to the principles of medical professionalism. These conflicts occur when physicians have motives or are in situations for which reasonable observers could conclude that the moral requirements of the physician's roles are or will be compromised. Although physician groups, the manufacturers, and the federal government have instituted self-regulation of marketing, research in the psychology and social science of gift receipt and giving indicates that current controls will not satisfactorily protect the interests of patients. More stringent regulation is necessary, including the elimination or modification of common practices related to small gifts, pharmaceutical samples, continuing medical education, funds for physician travel, speakers bureaus, ghostwriting, and consulting and research contracts. We propose a policy under which academic medical centers would take the lead in eliminating the conflicts of interest that still characterize the relationship between physicians and the health care industry.

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Most companies also support continuing medical education (CME). However, their ultimate fiduciary responsibility is to their shareholders who expect reasonable returns on their investments. Indeed, manufacturers are acutely aware of the conflict between patient vulnerability and profit incentives.

Recent congressional investigations, federal prosecutions, and class action lawsuits have brought to light documents demonstrating how company practices frequently cross the line between patient welfare and profit-seeking behavior.²⁻⁴ Concerned physicians, journalists, and federal prosecutors are exposing still other as-

pects of an unhealthy relationship between manufacturers and the medical profession.⁵⁻⁷

These transgressions have prompted pharmaceutical firms to regulate themselves more stringently. That effort is

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commendable, but physicians' behavior is a large part of the problem and industry efforts to date have not resolved the crisis. The standing of the profession, as much as the integrity of the pharmaceutical and medical device industries, is jeopardized by allowing obvious conflicts to continue.

The serious threat that this state of affairs poses for professionalism, and for the trust that patients have in physicians, makes the need for effective guidelines on industry-physician relationships both apparent and urgent. Marketing and market values should not be allowed to undermine physicians' commitment to their patient's best interest or to scientific integrity.

To remedy the situation and prevent future compromises to professional integrity, academic medical centers (AMCs) must more strongly regulate, and in some cases prohibit, many common practices that constitute conflicts of interest with drug and medical device companies. The guidelines we suggest are designed to promote broader professional self-regulation.

Why AMCs?

Academic medical centers, which include medical schools and their affiliated hospitals, should provide leadership for medicine in the United States. Just as pharmaceutical manufacturers look to AMCs for influential advice and support, so does the medical profession. Academic medical centers also have a major responsibility for training medical students and house staff. Research reveals that the habits learned or acquired during training persist into practice.⁸ Objectivity and scientific integrity should be central tenets of physician training.

Academic medical centers are also in a position to take immediate action. They are sufficiently well organized to gain commitments to a set of new principles in relatively short time. Moreover, independent research into the impact of medications and devices on population health is concentrated

in AMCs; therefore, unwarranted influence by manufacturers must be avoided. For these reasons, academic medicine should take the leadership in reforms, and other physicians and medical institutions should adopt their standards.

Defining Conflicts of Interest With Industry

Conflicts of interest occur when physicians have motives or are in situations for which reasonable observers could conclude that the moral requirements of the physician's roles are or will be compromised. In terms of industry influences, financial conflicts of interest occur when physicians are tempted to deviate or do deviate from their professional obligations for economic or other personal gain.⁹ The bias thus introduced violates both the best interests of patients and the standards of scientific integrity. Policing such conflicts clearly lies within the scope of professional responsibilities set forth in the *Physician Charter on Medical Professionalism*.^{10,11}

Traditionally, marketing by pharmaceutical and device companies has centered on company representatives or "detail persons" who visit individual physicians and provide information on new products. This practice has increased in scale and many other marketing strategies are also used. Approximately 90% of the \$21 billion marketing budget of the pharmaceutical industry continues to be directed at physicians, despite a dramatic increase in direct-to-consumer advertising.¹² In 2000, for example, the industry sponsored 314 000 events specifically for physicians.¹³ Moreover, industry contracted with many hundreds of physicians to serve on advisory boards or speakers bureaus.⁵ The purpose behind such industry contacts with physicians is unmistakable: drug companies are attempting to promote the use of their products.

The following list, while not exhaustive, indicates the interactions with industry that must be addressed¹⁴: gifts, even of relatively small items, includ-

ing meals; payment for attendance at lectures and conferences, including online activities; CME for which physicians pay no fee; payment for time while attending meetings; payment for travel to meetings or scholarships to attend meetings; payment for participation in speakers bureaus; the provision of ghostwriting services; provision of pharmaceutical samples; grants for research projects; and payment for consulting relationships.

These interactions have been examined by a variety of physician and industry groups, including the American Medical Association, the American College of Physicians, the Accreditation Council for Continuing Medical Education (ACCME), and the Pharmaceutical Research and Manufacturers of America.² The Office of the Inspector General of the Department of Health and Human Services has also released guidelines endorsing the Pharmaceutical Research and Manufacturers of America code.

In our view, the guidelines produced by these various groups and organizations are not sufficiently stringent and do not adequately uphold a professional commitment to patient welfare and research integrity. None of these groups establishes monitoring mechanisms or pinpoints responsibility for compliance. The profession itself must exert much tighter control over the relationships between manufacturers and physicians.

Myths of the Small Gifts and Full Disclosures

Most of the recommendations from medical and industry groups share 2 key assumptions. The first is that small gifts do not significantly influence physician behavior. The second is that disclosure of financial conflicts is sufficient to satisfy the need to protect patients' interests. Although these 2 assumptions are widely accepted among physicians, compelling research findings using a variety of methods have called their validity into question.

Psychologists, sociologists, and economists have explored human be-

behavior in a conflicted situation using innovative experimental techniques.¹⁵ Their research has established that behavior is not entirely rational, individuals are not always conscious of their motives, and many popular beliefs about how individuals act in light of specific information are simply wrong.¹⁶

Social science research demonstrates that the impulse to reciprocate for even small gifts is a powerful influence on people's behavior. Individuals receiving gifts are often unable to remain objective; they reweigh information and choices in light of the gift.¹⁷ So too, those people who give or accept gifts with no explicit "strings attached" still carry an expectation of some kind of reciprocity.¹⁷ Indeed, researchers suggest that the expectation of reciprocity may be the primary motive for gift-giving.¹⁵

Researchers have specifically studied industry gifts to physicians. Receiving gifts is associated with positive physician attitudes toward pharmaceutical representatives.^{18,19} Physicians who request additions to hospital drug formularies are far more likely to have accepted free meals or travel funds from drug manufacturers.²⁰ The rate of drug prescriptions by physicians increases substantially after they see sales representatives,²¹ attend company-supported symposia,²² or accept samples.^{23,24} The systematic review of the medical literature on gifting by Wazana²⁵ found that an overwhelming majority of interactions had negative results on clinical care.

The assumption that disclosure to patients is sufficient to resolve problems created by physicians' conflicts of interest is also unfounded. First, physicians differ in what they consider to be a conflict, which makes the disclosure of conflicts incomplete. Because declarations of conflict are usually unverified, their accuracy is uncertain. Second, recipients of information who are not experts in a particular field often find it impossible to identify a biased opinion that they read or hear about that subject.¹⁷ Third, disclosure may be used to "sanitize" a problematic situa-

tion, suggesting that no ill effects will follow from the disclosed relationship.²⁶ Rather than eliminate the conflict, it is easier to disclose it and then proceed as though it did not exist.⁵

More Stringent Regulation

Because gifts of even minimal value carry influence and because disclosure is an inadequate safeguard, the guidance presently provided by the medical profession, the pharmaceutical industry, and the federal government fails to protect the best interests of patients and the integrity of physician decision making. For these reasons, many current practices should be prohibited and others should be more strictly regulated to eliminate potential sources of unwarranted influence.

Gifts. All gifts (zero dollar limit), free meals, payment for time for travel to or time at meetings, and payment for participation in online CME from drug and medical device companies to physicians should be prohibited. A complete ban on these activities by eliminating potential gray areas greatly eases the burden of compliance. It also frees physicians from deciding whether a gift is appropriate and removes a principal mode by which detail persons gain access to physicians' offices and influence their decision making.

Pharmaceutical Samples. The direct provision of pharmaceutical samples to physicians should be prohibited and replaced by a system of vouchers for low-income patients or other arrangements that distance the company and its products from the physician. The availability of free samples is a powerful inducement for physicians and patients to rely on medications that are expensive but not more effective. Samples also provide company representatives with access to physicians. The increasing reliance on direct-to-consumer advertising by drug companies only heightens the tension between current marketing practices and good patient care.

Drug companies believe that the interactions between sales representatives and physicians serve several pur-

poses, which include introduction of physicians to new medications, encouragement to use the most effective medications, improvement of the likelihood that they will follow good practice guidelines, and access to medications for low-income patients. From the perspective of medical professionalism, however, far better methods for securing these goals exist, all of which would be free of the pitfalls of marketing strategies.

Drug Formularies. Hospital and medical group formulary committees and committees overseeing purchases of medical devices should exclude physicians (and all health care professionals) with financial relationships with drug manufacturers, including those who receive any gift, inducement, grant, or contract. These policies would help ensure that decision making for formulary drugs and medical devices is based solely on the best available scientific evidence.

Continuing Medical Education. The widespread influence of drug manufacturers on current CME activities makes more stringent regulation necessary.²⁷ Manufacturers should not be permitted to provide support directly or indirectly through a subsidiary agency to any ACCME-accredited program. Manufacturers wishing to support education for medical students, residents, and/or practicing physicians should contribute to a central repository (eg, a designated office at an AMC), which, in turn, would disburse funds to ACCME-approved programs. This arrangement would permit the central repository and the ultimate recipients of funds to remain free from influence by any one donor company. To ensure accountability and to acknowledge generosity, the amount of funds contributed and the eventual use of the funds should be posted on a publicly available Web site.

This policy would likely reduce the contributions made by drug and device companies to CME programs. Companies acknowledge that they carefully evaluate the market impact of expenditures and support only

those demonstrating an increased use of their products.²⁸ Other ways of funding CME programs will have to be identified.

Funds for Physician Travel. Pharmaceutical and device manufacturers interested in having faculty or fellows attend meetings should provide grants to a central office at the AMC. That office could then disburse funds to faculty and training program directors. Trainees would no longer be directly dependent on industry largesse for educational opportunities.

Speakers Bureaus and Ghostwriting. Faculty at AMCs should not serve as members of speakers bureaus for pharmaceutical or device manufacturers. Speakers bureaus are an extension of manufacturers' marketing apparatus. Because AMC faculty have a central role in the training of new physicians and represent their own institution, they should not function as paid marketers or spokespersons for medicine-related industries. By adhering to this recommendation, academic leaders will be upholding the principle that faculty opinion should be data driven and not for hire. For these same reasons, faculty should be prohibited from publishing articles and editorials that are ghostwritten by industry employees.

Consulting and Research Contracts. Because the process of discovery and development of new drugs and devices often depends on input from academic medicine, consulting with or accepting research support from industry should not be prohibited. However, to ensure scientific integrity, far greater transparency and more open communication are necessary. Accordingly, consulting or honoraria for speaking should always take place with an explicit contract with specific deliverables, and the deliverables should be restricted to scientific issues, not marketing efforts. So-called "no strings attached" grants or gifts to individual researchers should be prohibited. A contract with no identified deliverables is tantamount to a gift and should be regarded as such.²⁹

To promote scientific progress, AMCs should be able to accept grants for general support of research (no specific deliverable products) from pharmaceutical and device companies, provided that the grants are not designated for use by specific individuals. As long as the institution stands between the individual investigator and the company making the grant, the likelihood of undue influence is minimized but certainly not eliminated.

To better ensure independence, scientific integrity, and full transparency, consulting agreements and unconditional grants should be posted on a publicly available Internet site, ideally at the academic institution. This is important because company-funded research is more likely to produce positive results and on occasion companies have restricted the dissemination of research results unfavorable to their products.³⁰

One might argue that such an approach simply transfers the pressure surrounding financial conflicts to the institution and, as in the case of Oliveri at the University of Toronto, institutions have given in to pressure from pharmaceutical firms.³¹ But the requirements of public access and peer pressure will more effectively operate at the institutional level and such a policy is preferable to banning all contact between manufacturers and academic centers.

Going Forward

The benefits of such policies may convince the leadership of AMCs and medical schools to adopt them. We realize that some AMCs will be concerned that voluntarily adopting more stringent regulations may put them at a competitive disadvantage compared with those that do not.³² However, we hope their leadership will recognize that we call for changes in current AMC practices that are, in many respects, modest. For example, existing guidelines prohibit all gifts from industry except those that are small; going one step further and eliminating token gifts should not cause great disruption and may bring greater clar-

ity. Grants and consulting are not prohibited but must be transparent and subject to peer review. Although such steps may cause significant challenges for medical schools and affiliated institutions, students, physicians, and the public deserve unbiased medical education, research, and clinical care.

Industry has good reason to accommodate itself to these policies and will continue to seek assistance from academic consultants and researchers. Commercial entities working with AMCs cannot be pleased about the diminished respect and growing public mistrust of their activities in the current environment.

Medical schools must be prepared to monitor compliance and enforce the rules we have outlined. There will be costs associated with oversight and perhaps a decline of collegiality among faculty. But these negative aspects will depend to some extent on the prevalence of violations. If AMC leaders educate colleagues and build a consensus around these principles, compliance will follow.

What then might the world of medicine look like if these proposals are widely adopted? First, decisions by physicians on which prescription to write and which device to use might become more evidence-based; medical societies' practice guidelines might become less subject to bias. A greater reliance on objective sources for accurate and up-to-date information would also promote better patient outcomes. Second, total expenditures on prescription drugs might decline. An increased use of generic products, increased use of comparable but less expensive patent-protected products, and, in some cases, a decreased reliance on pharmaceutical agents might be observed. Third, although AMCs and professional societies would have to find alternative sources for funding programs, the absence of industry representatives at AMC meetings and lunches and in corridors would increase the sensitivity among medical students and house staff to the values of medical professionalism and scientific integrity.

Rules would be standardized, not, as now, with some departments prohibiting drug company lunches, others allowing them; some hospitals permitting the sales representatives to see their physicians, others not. Medical society meetings would also assume a more professional tone and the substance

of the programs would become more scientific.

Ultimately, the implementation of these proposals will substantially reduce the need for external regulation to safeguard against market-driven conflicts of interest, and the medical profession will reaffirm very publicly its

commitment to put the interests of patients first.

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