Gifts to Health Care Professionals from the Pharmaceutical Industry

A Report by the National Ethics Committee of the Veterans Health Administration

October 2003

National Center for Ethics in Health Care
Veterans Health Administration
Department of Veterans Affairs

Founded in 1986, the National Ethics Committee (NEC) of the Veterans Health Administration (VHA) is an interdisciplinary group authorized by the Under Secretary for Health through the National Center for Ethics in Health Care. The NEC produces reports on timely topics that are of significant concern to practicing health care professionals. Each report describes an ethical issue, summarizes its historical context, discusses its relevance to VHA, reviews current controversies, and outlines practical recommendations. Previous reports have been useful to VHA professionals as resources for educational programs, guides for patient care practices, and catalysts for health policy reform. Scholarly yet practical, these reports are intended to heighten awareness of ethical issues and to improve the quality of health care, both within and beyond VHA.

Executive Summary

The pharmaceutical industry spends billions of dollars annually on gifts to physicians Often these gifts consist of items that are designed to enhance patient care (e.g., anatomical models) or learning (e.g., textbooks), but gifts may also be of a more personal nature (e.g., event tickets). Serious ethical concerns have been raised that gifts from the pharmaceutical industry to individual health care professionals risk compromising health care providers' professional objectivity and integrity, and/or undermining their fundamental ethical commitment to putting the interests of patients first.

This report discusses the special nature of gift relationships, examines why gifts to health care professionals from the pharmaceutical industry may be ethically problematic, and reviews professional ethical guidelines and legal standards regarding acceptance of gifts. The report recommends that facilities develop policies to:

1. Establish a culture that encourages behavior by health care professionals or institutions that prevents influence by pharmaceutical companies. E.g., emphasizes prohibitions that limit gifts, such as hospitality at an expensive restaurant.

2. Reinforce awareness that every VHA employee must comply with federal law prohibiting actions that might result in, or create the appearance of, using public office for private gain, as might occur when an employee accepts a gift.

3. Assure that ethical requirements apply consistently to all persons who care for patients under VHA authority. Policies regarding gifts should apply equally to all health care professionals, trainees, and contractors, whether the individual is or is not specifically bound by regulations applicable to federal employees of VHA.

4. Clearly and vigorously discourage workplace interactions between pharmaceutical representatives and health care professionals and trainees. Facilities should:

   (a) critically examine their policies and practices with regard to such interactions,

   and they should take steps to

   (b) limit pharmaceutical representatives' access to staff and trainees in the workplace,
   (c) minimize reliance on external, commercial sponsorship of educational programs for staff, and
   (d) discourage use of commercially sponsored patient education materials that display company logos.

5. Assure that where policies differ from those of affiliates, the facility holds to at least as rigorous a standard.

Introduction

Health care professionals who prescribe pharmaceutical products base their prescription decisions on many factors including effectiveness, safety, and cost. In an effort to influence practitioners' prescribing practices, the pharmaceutical industry employs diverse marketing and promotional strategies, among them offers of free drug samples, educational materials, meals, and other forms of gifts. These efforts are both intensive and expensive. In 2001 the drug industry spent more than $16 billion on visits to physicians' offices. In the last five years the number of pharmaceutical company sales representatives in the U.S. has increased from 42,000 to 88,000.[1] Some 80% of physicians report having been offered cash or gifts from pharmaceutical industry representatives.[2] Many physicians meet with pharmaceutical industry representatives four or more times per month.[3] Serious ethical concerns have been raised about these contacts between the pharmaceutical industry and individual health care professionals, especially when gifts are involved.[4-9]

The practice of accepting gifts from pharmaceutical industry representatives risks compromising health care providers' professional objectivity and integrity, and undermining their fundamental ethical commitment to putting the interests of patients first. Gift incentives to participate in continuing professional education programs are the wrong incentives for health care professionals and trainees, who should be independently motivated to participate in lifelong learning.[7] And there are economic consequences when the costs of gifts are passed along to patients, health care institutions, and third-party payers in the form of higher prices for drugs. Escalating drug costs may ultimately result in limitations on access to care.

Federal regulations (at 5 CFR, Part 2635) establish standards for conduct in relation to gifts for all federal employees. But anecdotal reports from the field indicate that beyond these mandated thresholds, local facilities' policies about accepting gifts from the pharmaceutical industry vary widely within VHA. To address this state of affairs, new national policy limits the access representatives of the pharmaceutical industry may have to facilities and staff.[*] This national guidance provides a foundation for the development of more uniform local policies throughout the system.

This report by the VHA National Ethics Committee examines the values at stake in relationships between practitioners and the pharmaceutical industry from the perspective of health care ethics. Its goal is to clarify the philosophical and professional concerns that underlie regulations and policy in this area.

The report addresses gifts provided to individual health care professionals by representatives of the pharmaceutical industry. Often these gifts consist of items that are designed to enhance patient care (e.g., reflex hammers, anatomical models) or learning (e.g., meals at educational events, textbooks), but gifts may also be of a more personal nature (e.g., organizers, event tickets). The promotional nature of gifts may be subtle or obvious, depending on, for example, whether a sponsor or product name is prominently displayed. For this report gifts are distinguished from purely promotional items that have no intrinsic value to the recipient (e.g., product brochures) and from compensation for professional work (e.g., honoraria).

The report discusses the definition of gifts, examines why gifts to health care professionals from the pharmaceutical industry may be ethically problematic in the health care setting, and reviews professional ethical guidelines and legal standards regarding acceptance of gifts. It offers practical recommendations to guide ethical policy within VHA. Although the analysis and recommendations offered here were developed specifically in reference to gifts from pharmaceutical representatives,

[*]VHA Directive 2003-060, Business Relationships Between VA Staff and Pharmaceutical Industry Representatives.

they apply equally to gifts from representatives of medical manufacturers.[10, 11] Gifts provided to institutions are beyond the scope of this report.[*]

What Is a Gift?

Webster defines a gift as: "something bestowed voluntarily and without compensation."[12] Although this definition captures our casual understanding of a gift as something given with no expectation that the recipient will reciprocate, it misses much of the social aspect of gifts that make gifts from pharmaceutical representatives to health care professionals ethically challenging. Gifts "have deep and sometimes contradictory cultural meanings."[13] Unlike contracts, in which parties set out clear, explicit expectations, gifts place people in binding personal relationships that generate vague, open-ended moral obligations. The importance of a gift lies in the personal relationship it generates, sustains, and signifies.[14]

Why Are Gifts Ethically Problematic?

Because gifts create relationships, health care professionals' acceptance of gifts from the pharmaceutical industry can be ethically problematic in several ways. Accepting gifts risks undermining trust. It may bias clinicians' judgments about the relative merits of different medications. And it may affect prescribing patterns in ways that increase costs and adversely affect access to care.

Undermining Patient & Public Trust. Health care professionals' fiduciary, or trust-based, relationship with patients requires that practitioners explain the reasons for treatment decisions and disclose any potential conflicts of interest, including the influence of gifts. One study asked patients and physicians to rate how appropriate it would be for a physician to accept gifts (ranging from pens to trips) from the pharmaceutical industry, and whether they thought accepting gifts would influence the physician's behavior.[15] With the exception of drug samples, the patients considered gifts to be more influential than did the physicians. Almost half of the patients who participated had not been aware that physicians received gifts from pharmaceutical companies—and of those, 24% said that this new knowledge changed their perception of the medical profession. Similarly, a telephone survey of patients found that although 82% of respondents were aware that physicians received "office-use gifts" from the pharmaceutical industry, only about one-third were aware that physicians received personal gifts.[16] Forty-two percent believed that personal gifts adversely affect both the cost and the quality of health care. On the basis of such data, the American College of Physicians has concluded that "[a] significant number of patients believe that industry gifts bias their physician's prescribing practices and ultimately drive up medical costs."[17] Public awareness that health care professionals accept gifts from pharmaceutical representatives may undermine trust in the profession and lead to a perceived loss of professional integrity.

VHA is a public agency and public service is considered a public trust. Consequently, the public rightly hold VHA to a higher ethical standard than they do private companies. As federal employees, health professionals appointed to VHA have an obligation to ensure that citizens can have complete

[*] For discussion of gift relationships between physicians and *patients*, see the report of the National Ethics Committee, *Ethical Boundaries in Patient-Clinician Relationships*, available at http://vaww.va.gov/vhaethics/download/boundariesjuly03.doc.

confidence in the integrity of the federal government (5 CFR 2635.101; EO 12674). Whereas the public relies on legal enforcement mechanisms to assure that private health care organizations comply with relevant law and regulation, they expect public agencies and employees to adopt policies that not merely follow the rule of law but also promote its spirit by establishing goals of exemplary behavior as ethical standards. Acceptance of any type of gift from the pharmaceutical industry by VHA employees risks eroding public trust in VHA, possibly to a greater degree than would be the case for employees in private agencies. More importantly, the beneficiaries of government programs—veterans, in the case of VHA—are often more dependent on government services than are those who rely on private programs. This greater dependence gives rise to the government's obligation to adhere to a stricter ethical standard.

Effects on Professional Relationships. Given the ways in which gift giving differs from entering into a contractual relationship, gifts from pharmaceutical representatives to health care professionals can blur the distinction between formal business exchanges and informal, interpersonal exchanges.[13] The social experience of giving and receiving gifts affects the relationship between the two parties in complex and subtle ways. Anthropological literature[13] explains that the recipient of a gift often feels three types of obligation toward the giver: grateful conduct (i.e., acceptance of the gift and expression of gratitude), grateful use (i.e., in accord with the giver's intention), and reciprocation. Obligations to accept the gift and thank the giver and to use the gift as the giver intended stem from the purpose of gift exchange—building personal, moral relationships.

The felt obligation to reciprocate, to give or do something in exchange for the gift is most troubling in the health care context. As Murray notes, "Appropriate reciprocation depends on particular cultural norms and the specifics of the relationship."[13] In the context of a gift to a health care professional from a pharmaceutical industry representative, practitioners commonly understand that the hoped for reciprocation involves the health care professional writing more prescriptions for the drug(s) the representative is promoting.

Bias & Conflicts of Interest. Health care professionals may be influenced by accepting gifts in two ways. As we have noted, they understand that prescribing selected pharmaceutical products is the industry's preferred form of reciprocation, and some may be influenced to do so in response to the gift received. One study, for example, found that physicians who met with or accepted money from representatives of pharmaceutical companies (e.g., for educational presentations) were more likely to request that the companies' drugs be added to a hospital pharmacy than were colleagues who did not interact with pharmaceutical companies.[18] A review of physicians' prescribing patterns found that usage of two drugs increased significantly among physicians who attended "all-expense-paid" symposia at resorts sponsored by the manufacturer of the drugs compared to their practice before the symposia.[19] The majority of physicians responding did not believe that such incentives would alter their prescribing practices. Similarly, a recent study reported that British general practitioners who had weekly contact with drug company representatives were more willing to prescribe new drugs and more likely "to express views that will lead to unnecessary prescribing" than general practitioners with less frequent contact with pharmaceutical representatives.[20]

The second concern is that gifts may insidiously introduce undetected or under appreciated bias into professionals' assessment of the overall merit or value of promoted pharmaceutical products. There is evidence to indicate that practitioners themselves are often poor judges of whether or when external factors, such as gifts, influence their decision making.[3, 15, 21–23] For example, 86% of respondents to a nurse practitioner and physician assistant survey regarding pharmaceutical industry

promotions said "it is appropriate to accept gifts and that these gifts do not influence their prescription choices."[24]

Pharmaceutical industry gifts to health care professionals create potential conflicts of interest that can affect practitioners' judgment—without their knowledge and even contrary to their intent—thereby placing professional objectivity at risk and possibly compromising patient care.[4] Trainees may be especially susceptible to conflicts of interest created by gifts. This influence is also detectable among physicians in training and other prescribing professionals. For example, more than half of psychiatric trainees responding to a questionnaire about interactions with the pharmaceutical industry felt that receiving gifts would not influence their prescribing practices. Moreover, "[t]he more money and promotional items a physician-in-training had received, the more likely he or she was to believe that discussions with representatives did not affect prescribing."[25] A study of housestaff reported that residents generally do not find gifts from industry problematic and do not believe that they are influenced by them.[26] The study found, however, that residents' behavior was not consistent with their expressed attitudes. For instance, every resident who considered pharmaceutical industry sponsored conference lunches and pens inappropriate had nonetheless accepted these gifts. Another study reported that the more exposure trainees had to pharmaceutical industry representatives, the higher they rated the general appropriateness of gift acceptance.[27] Yet other research reported that 90% of trainees surveyed acknowledged that pharmaceutical industry representatives in fact were influencing their prescribing practices.[28]

Effects on Health Care Costs. Gifts from the pharmaceutical industry to health care professionals are not "free." The pharmaceutical industry's expenditures for the promotion of prescription drugs, including gifts, are significant, totaling $15.7 billion in 2000.[29] While health care professionals are the beneficiaries of gifts, the cost of these marketing tools is passed through to purchasers and increases the costs of pharmaceutical products in two ways. First, expenditures for gifts are passed along to consumers in the form of higher prices. Second, if gifts to professionals serve their purpose, practitioners will be influenced to prescribe heavily marketed drugs, which tend to cost far more than less heavily marketed but often equally effective alternatives, such as generic drugs. Data from Great Britain suggest that use of new drugs and higher prescribing costs are "strongly and independently associated" with frequent interactions between health care professionals and pharmaceutical representatives.[20] Rising health care costs can lead to limitations on access to care.

Why Are Gifts Accepted?

If accepting gifts from the pharmaceutical industry is ethically problematic in these ways, why do health care professional continue to take the pens, textbooks, drug samples, meals, and other gifts they are offered? One explanation is that accepting a gift is a natural, socially expected reaction motivated by a combination of self-interest and politeness. But it is also argued that health care professionals and trainees have come to expect gifts as part of a "culture of entitlement" that has evolved as a result of years of largesse on the part of pharmaceutical companies.[5] Gifts have become a familiar part of many health care workplace cultures and established patterns of behavior often resist change.

Other rationales are that inducements such as free lunches are needed to induce attendance at educational sessions (and may help offset the costs of such programs),[30] and that they help boost employee morale. Some even claim that accepting gifts results in economic savings for health care

institutions,[30] because the pharmaceutical industry provides for free items that the institutions would otherwise have to buy. Finally, apathy on the part of professional bodies allows the "tradition" of accepting gifts to continue. Failure to enforce ethical standards consistently has made it easier simply not to notice, or not to be concerned about, the fact that accepting gifts creates ethical risks.

None of these arguments, however, is compelling enough to allow an ethically problematic practice to continue. While habit and self-interest can be powerful motivators, ethical standards explicitly require health care professionals to place patient interests above their own. The Accreditation Council for Graduate Medical Education (ACGME), which oversees all physician residency programs in VHA, has established important ethical principles to guide relationships with the pharmaceutical industry. One principle is that teaching institutions must ensure that their training programs have sufficient funds from appropriate sources to conduct their educational activities so as to reduce or eliminate the risk of undue influence.[31]

Moreover, any potential cost savings resulting from gifts is likely to be far outweighed by undesirable effects on prescribing practices: gifts influence health care professionals to prescribe more expensive medications without a measurable positive effect on patient care, resulting in increased, rather than decreased pharmaceutical costs overall.[18, 19] Moreover the Accreditation Council for Continuing Medical Education has concluded that commercially sponsored educational events are far more costly than they need to be.[32]

Professional, Ethical & Legal Standards

In recent years, many prominent organizations and associations have established ethical guidelines for health care professionals about accepting gifts from the pharmaceutical industry. These guidelines do not prohibit *all* gifts from industry—as the Code of Medical Ethics of the American Medical Association (AMA) notes, gifts may "serve an important and socially beneficial function," such as supporting educational programs. But there is general agreement that gifts from pharmaceutical companies to health care professionals and trainees are acceptable only when the primary purpose is "the enhancement of patient care and medical knowledge."[17, 33, 34]

The American College of Physicians position paper on physician-industry relations makes clear that permitting the acceptance of some gifts from industry is by no means the same as encouraging the practice:

> The acceptance of individual gifts, hospitality, trips, and subsidies of all types from industry by an individual physician is strongly discouraged. Physicians should not accept gifts, hospitality, services, and subsidies from industry if acceptance might diminish, *or appear to others to diminish*, the objectivity of professional judgment.[16] (emphasis added)

Professional guidelines seek to establish thresholds for what kinds of gifts and gift relationships are acceptable. In general, gifts to individual practitioners are discouraged unless they are of minimal value and related to the practitioner's work—such as pads, pens, or calendars for office use.[17] The American Medical Association, American College of Physicians, and American Association of Orthopaedic Surgeons (AAOS) permit modest gifts of an educational nature, such as medical books, or modest hospitality in conjunction with a legitimate educational program.[17, 33, 35] Guidelines generally permit subsidies for continuing medical education conferences, so long as they are paid to conference sponsors, not individual participants, and sponsors are prohibited from imposing any restrictions with regard to substantive content of presentations.[31, 35] The AMA and AAOS would

similarly permit subsidies for trainee participation in "major educational, scientific or policy-making meetings of national, regional or specialty medical associations" so long as recipients of funds are selected by their academic or training institutions.[33, 35]

The American Medical Student Association takes a sterner view. Its policy on pharmaceuticals and medical devices urges health care professionals not to accept *any* promotional gifts from pharmaceutical companies or honoraria for speaking on behalf of industry at educational conferences. It calls on hospitals and residency programs "to discontinue the practice of company-funded lectures and lunches," and recommends that they stop "disseminating information about off-site, industry-sponsored events."[36]

Some facilities have followed this line of argument and implemented policies that strive to set the highest possible standards. For example, one local policy places strict limits on pharmaceutical representatives' access to staff. Its policy reads, in part:

> Pharmaceutical Sales Representatives are prohibited from visiting the medical center for any business-related purpose, except under the following conditions:
>
> > (1) When visits to the medical center by a Pharmaceutical Sales Representative have been authorized by Chief of Pharmacy, with Chief of Staff approval, for the purpose of coordinating the procurement or recall of a particular product, or obtaining technical or professional information, and an appointment has been scheduled.[37]

The policy further prohibits training that is provided for purposes of promoting products or services ("vendor promotional training"), expect when training is provided "to facilitate use of products or services" furnished under a government contract. Pharmaceutical representatives are permitted to provide information and education only about products included in the medical center formulary, and only in response to requests from designated institutional officers.

Finally, in July 2002 the Pharmaceutical Research and Manufacturers of America (PhRMA) promulgated a voluntary code for its member companies to guide their interactions with health care professionals and institutions. The PhRMA code sets substantially similar standards to those adopted by health care professional organizations and associations. Although it is not binding, and is predicated on industry's continuing promotional activities, the code recognizes the need to minimize "inappropriate" kinds of contact between health care providers and industry representatives and sets standards for members with regard to sponsorship of educational conferences (including choice of venue), consultation arrangements with health care professionals, and educational funds and materials.[34]

In addition to the ethical concerns about acceptance of gifts from pharmaceutical companies, there are legal considerations. Health care professionals employed in VHA are subject to federal conduct regulations and conflict of interest laws that do not apply in the private sector. For example, the Standards of Ethical Conduct for Employees of the Executive Branch, 5 CFR Part 2635, would prohibit acceptance of gifts from pharmaceutical companies by VA practitioners in most of the situations previously described in this report. Moreover, a VA practitioner may not solicit gifts from a drug company under any circumstance. They also cannot accept a gift in exchange for acting to influence an agency decision, e.g., requesting that a drug be added to the formulary. VA health care professionals also cannot accept gifts that result in or appear to involve use of their public office for private gain. For example, if a VA physician were to repeatedly accept a drug manufacturer's offer to pick up the lunch tab at their regular meetings, it might appear that lunch was being provided in

order to reward or encourage that physician to continue recommending the company's product to VA patients. These and other rules that limit the acceptance of gifts from pharmaceutical companies require interpretation. There is also the potential for criminal as well as administrative sanctions if these rules concerning gifts are violated. Further, practitioners should be mindful of federal statutes governing the area of health care fraud and abuse, including the federal health care program anti-kickback statute (42 U.S.C. 1320a-7b(b); see also 42 C.F.R. 1001.952). We strongly urge VA health care professionals who have questions about legal standards regarding gifts or other interactions with pharmaceutical companies and medical manufacturers to seek guidance from their local Regional Counsel or General Counsel.

Recommendations

We find ethical arguments for limiting gifts from the pharmaceutical industry compelling and recommend that VHA facilities adopt policies to restrict the opportunities for health care professionals and trainees to be offered and influenced by gifts or other incentives from pharmaceutical representatives. The National Ethics Committee recognizes that VHA facilities operate in a complex health care environment and sustain close, ongoing relationships with academic affiliates and other health care organizations in an effort to provide the highest quality care. As a public body, however, VHA has an obligation to uphold the public trust and should be held to a higher standard than its private sector partners. We urge VHA networks and facilities to adopt robust policies that have the following features (these recommendations are consistent with VHA policy):

(1) Establish a culture that encourages behavior by health care professionals or institutions that prevents influence by pharmaceutical companies. E.g., emphasizes prohibitions that limit gifts, such as hospitality at an expensive restaurant.

(2) Reinforce awareness that every VHA employee must comply with federal law prohibiting actions that might result in, or create the appearance of, using public office for private gain, as might occur when an employee accepts a gift.

(3) Assure that ethical requirements apply consistently to all persons who care for patients under VHA authority. Policies regarding gifts should apply equally to all health care professionals, trainees, and contractors, whether the individual is or is not specifically bound by regulations applicable to federal employees of VHA.

(4) Clearly and vigorously discourage work place interactions between pharmaceutical representatives and health care professionals and trainees. In accordance with national policy, facilities should:

(a) critically examine their policies and practices with regard to such interactions,

and they should take steps to

(b) limit pharmaceutical representatives' access to staff and trainees in the workplace,

(c) minimize reliance on external, commercial sponsorship of educational programs for staff, and
(d) discourage use of commercially sponsored patient education materials that display company logos.

(5) Assure that where policies differ from those of affiliates, the facility holds to at least as rigorous a standard, and ideally sets an example to which partnering organizations should aspire.

Conclusion

The social dynamics of the gift relationship, the potential for gifts subtly to bias health care professionals' prescribing practices and clinical decisions, and the obligation of health care professionals within VHA, as public servants, to avoid acting in ways that might undermine public trust all argue for the adoption of clear, robust policies regarding the acceptance of gifts from pharmaceutical companies. Creating a workplace in which professionals no longer routinely expect or accept gifts from industry is a challenging task that calls for professional role modeling and sustained, coordinated efforts on the part of clinical and administrative leaders, as well as development and careful implementation of clear, well-considered policy.

The NEC commends facilities and VISNs that have implemented policies that place strict limits on interactions between health care professionals and trainees and representatives from the pharmaceutical industry. All VHA facilities should discourage professionals and trainees from using promotional materials, especially where they can be seen by patients, and should regularly offer educational sessions for trainees and staff that specifically address types and sources of bias in prescribing medications. Only in this way will we fulfill our duty as government employees and health care professionals entrusted to serve the public interests and put the interests of our patients above our own.

Acknowledgment: The authors gratefully acknowledge the contributions of Linda Ganzini, MD.

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