Gifts to Emergency Physicians from the Biomedical Industry

This policy resource and education paper (PREP) was developed as an explication of the ACEP policy statement "Gifts to Emergency Physicians from Industry"

Over the last two decades there has been steadily increasing attention paid to the relationships between physicians and the biomedical industry, including industry funding of biomedical research, sponsorship of continuing medical education programs, and the marketing of drugs and devices to physicians. In 2001 the U.S. pharmaceutical industry spent an estimated $21 billion promoting the sale of prescription drugs. It is estimated that 84% of pharmaceutical marketing is directed toward physicians, including free samples, journal ads, and visits from sales representatives.

There has been a great deal of spirited debate, among those interested in the ethical implications of these relationships, regarding the influence of industry largesse upon practice patterns and prescribing behaviors of physicians.

This Policy Resource and Education Paper (PREP) will focus specifically on the ethical debate surrounding the acceptance, by emergency physicians, of gifts from the biomedical industry.

A "white paper" published in 2002 by the Accreditation Council on Graduate Medical Education[i] sets forth the background against which the issues must be considered:

Benefits to patients result from services provided by both doctors and drug companies. Closer scrutiny, however,…reveals irreconcilable differences. [T]he responsibility of the pharmaceutical industry [is] to act in the best interests of its shareholders by maximizing their return on investment. In contrast, however, the altruism expected of medical professionals dictates that doctors put patients first. The doctor-patient relationship…is the foundation of medical professionalism; the good of the patient must be preeminent.

The conflict of values between the professional ethics of the physician and the business ethics of industry is impossible to ignore. Nowhere is this conflict more apparent than in the conduct of promotional activities. Industry engages in advertising campaigns and associated marketing activities because they work; successful promotion increases shareholder value. It is the chief means by which industry relates to physicians, residents, and medical students.

Unfortunately, such promotional [activity] has been proven to influence medical decision making, and studies have found decision makers unable to recognize its impact.

Gifts from industry to physicians take many forms, and may include the pens and notepads that are ubiquitous in doctors' offices and throughout hospitals, including emergency departments; reference tools, such as sponsor-labeled copies of the Sanford Guide to antibiotic usage and even major emergency medicine textbooks; snacks and food provided to ED staff on duty or to residents for their regular conferences; and invitations to hear drug-company-sponsored "educational" presentations at a posh restaurant or local country club.

The common theme underlying all of these gifts is marketing: the effort by the manufacturer of a drug or biomedical device to influence the practice patterns and prescribing behaviors of physicians.

Recent Historical Background

In 1980 a medical student posed a question to John C. Moskop, Ph.D., a bioethicist at the Brody School of Medicine: "My classmates and I are being offered medical bags, stethoscopes, and other items by different drug companies. Most are happy to accept these gifts, but I am not comfortable with this. Is this a genuine ethical

issue?" This question led to the publication of an article on the subject, in which the authors stated, "Because gifts may inappropriately influence physician attitudes, and because they increase the cost of drugs to patients, *only those gifts which promise a significant benefit to patient care may be accepted*."[ii]

Later in the same decade, two of the foremost medical journals in the U.S. included articles addressing the matter and contained the following assertions.

> It is unacceptable and unethical that physicians should acquiesce in practices that may create bias and loss of objectivity or that result in conflicts of interest affecting their care of patients.[iii]
>
> We must acknowledge the ethical dangers inherent in situations in which physicians accept gifts or other favors from drug companies.
> Given the moral complexities and dangers in gift giving, we feel that professional societies should establish guidelines for physicians' actions in these situations.[iv]

The authors of the previously quoted article in *JAMA* were not alone. As government agencies, consumer advocacy organizations, and physicians themselves became ever more acutely aware of the potential for untoward influence that comes with the industry representatives bearing gifts to physicians, there were many calls for professional associations to develop and promulgate guidelines for their members to follow. The American College of Emergency Physicians, the American Medical Association, and the American College of Physicians are just a few that have done so. The American College of Physicians (now combined with the American Society of Internal Medicine [ACP/ASIM]) published this statement in 1990:

Gifts, hospitality, or subsidies offered to physicians by the pharmaceutical industry ought not to be accepted if acceptance might influence *or appear to others to influence* the objectivity of clinical judgment. A useful [test to apply is]: Would you be willing to have these arrangements generally known?[v] (Emphasis added.)

ACEP policy – approved by the Board of Directors in September 1992 and most recently revised in June 2002[vi] – takes the position that "Gifts to emergency physicians should be of minimal value and should either benefit patients or serve a genuine educational purpose."

The Society for Academic Emergency Medicine, in its policy[vii] adopted in 1991, notes that physicians must understand the subtle effects and obligations of accepting even educational or trivial gifts and ensure that the practice does not unduly affect clinical decisions. Physicians should be willing and able to publicly reveal all gifts and financial arrangements with biomedical companies.

In 2001 even the pharmaceutical industry recognized the intensifying scrutiny of its interactions with physicians and provided several hundred thousand dollars to support the American Medical Association's efforts to educate U.S. physicians about the AMA's policy and ethical opinions on gifts to physicians. The following year the Pharmaceutical Research & Manufacturing Association (PhRMA) developed its own set of guidelines, the "PhRMA Code on Interactions with Healthcare Professionals."

At its spring 2002 Annual Meeting, the American Medical Student Association (AMSA) adopted the following straightforward position:

The American Medical Student Association urges all physicians, residents, and medical students not to accept as end recipients any promotional gifts from the pharmaceutical industry.

Some interesting insights into the views of those who supervise the teaching of students and residents were obtained in a survey[viii] of the members of the Council of Emergency Medicine Residency Directors (CORD). The majority of program directors (72%) "never" or "very rarely" allowed unrestricted interactions between pharmaceutical representatives and residents at work. However, only 52% of program directors said they "never" or "very rarely" allowed pharmaceutical representatives to give residents free drug samples at work. Only 46% said they "never" or "very rarely" allowed pharmaceutical representatives to teach residents. Two thirds of program directors desired CORD guidelines regarding interactions with the pharmaceutical industry. But if residency directors were looking for guidance on what sort of interactions to allow between residents and industry

representatives, they didn't get much in the way of specifics from the position subsequently adopted by CORD's Board:

The Council of Emergency Medicine Residency Directors (CORD) believes that emergency medicine (EM) residents should receive training regarding conflicts of interest that may arise from the promotion and marketing efforts of industry, primarily the pharmaceutical industry. Furthermore, EM residents should be instructed in critical appraisal methods so that unbiased judgments can be made regarding the efficacy of industry products. Residency programs should create policies that guide residents in dealing with pharmaceutical company representatives, potential conflicts of interest, and acceptable resolutions of these conflicts.[ix]

In short, the position taken by CORD is that program directors are free to do whatever they want, so long as they teach their residents to be skeptical of the pharmaceutical industry as a source of unbiased information about its products. To its credit, "CORD strongly supports the Accreditation Council for Graduate Medical Education (ACGME) white paper on the relationship between graduate medical education and industry and encourages its adoption by members."

The Current Reality

What do practicing emergency physicians do in real life? What *should* they do? Is there a gap between the status quo and the ethical ideal?

Perhaps the easiest – and most ethically defensible – approach would be, to borrow a slogan from the Reagan-era "war" on illicit drugs – "Just say NO" – essentially the position taken by AMSA. Many emergency physicians do just that, routinely refusing to meet or talk with drug company detail reps[x] – by either personal, departmental, or institutional policy – and never accepting even the most modest gifts, be they pens, sticky notes, or the occasional slice of pizza during a hasty lunch break in a busy shift.

At the other extreme are those who eagerly accept all such industry largesse. They take delight in their collections of pens and novelty items bearing the names of drugs and company logos; openly (and without a hint of shame) ask detail reps who visit the ED early in a day shift to come back later and bring lunch; and never hesitate for a moment to accept an invitation to listen to a brief "CME" talk at an expensive steak house, perhaps with tickets to a sporting event that directly follows thrown into the bargain. If they happen to be identified as "thought leaders" or "opinion leaders" in their institutions or communities (it helps to serve on, or even chair, the Pharmacy & Therapeutics Committee), they will enthusiastically accept invitations to attend conferences at luxurious resorts where their views as "consultants" will be sought regarding topics related to the sponsoring company's products.

It is likely that most emergency physicians fall, in their inclinations regarding gifts from industry, somewhere between these two approaches. They see little or no harm in accepting gifts of very modest value (such as pens and notepads) and don't believe that the "reminder" effect of such items has any influence on their practice patterns.[xi,xii] They are also unlikely to discern any ethical quandary in partaking of the occasional doughnut or slice of pizza left in the staff kitchen by a drug detail rep. Upon reflection, however, they realize that the outing to the steakhouse and sporting event is little more than an expensive social affair featuring overt advertisement of a company's products, designed to induce in them a sense of obligation to repay the kindness of the (personally attractive) company rep by prescribing the drug(s) being marketed.

Gifts from the pharmaceutical industry continue to be pervasive in many clinical and educational environments. One recent study identified a mean of forty-two advertising items found in ED clinical areas in the United States. The same study also identified significantly fewer items in departments with policies limiting contact with pharmaceutical representatives.[xiii]

There is an abundance of evidence that even gifts of minimal value do, indeed, influence physician practice patterns and prescribing behavior.[xiv,xv] Interestingly – even amusingly – most physicians believe they are not influenced by such gifts, or by their interactions with company reps, while at the same time readily agreeing that many of their colleagues *are* significantly influenced by the very same marketing efforts to which they believe themselves to be immune.[xvi]

Ethical Arguments

Arguments in favor of accepting gifts are several.

1. Physician autonomy: physicians should be free to associate with whomever they choose, including industry representatives; give and receive gifts; and enter into formal and informal business arrangements.
2. Benefits to patients
    a. Samples provide access to drug therapy for indigent patients, convenience for others.
    b. Industry representatives provide timely information on drug therapy to busy physicians.
    c. Educational gifts and events increase physician knowledge and thereby improve patient care.
3. Benefits to physicians
    a. Gifts provide clear benefits to physicians in an era of shrinking reimbursement.
    b. Physicians may act to enhance their own interests provided that the interests of others are not significantly harmed.
    c. Educational benefit of sponsored conferences (particularly unrestricted educational grants).
4. Freedom from bias
    a. Physicians can accept gifts from industry and still make unbiased clinical judgments about drug therapy.
    b. Interaction with multiple drug company representatives can prevent the potential bias of hearing only a single perspective.

There are corresponding arguments against accepting gifts.

1. Compromised objectivity
    a. Gifts create feelings of goodwill and indebtedness that do, in turn, influence choices of therapy (mostly unconsciously) for the wrong reasons.
    b. Information from drug representatives is not reliable, since its primary purpose is to persuade physicians to use certain drugs.[xvii]
    c. One study demonstrated a three-fold increase in the use of a particular drug following grand rounds sponsored by a pharmaceutical company.[xviii]
2. Financial harm to patients
    a. The cost of gifts to physicians – including "free" samples – is ultimately borne by patients in the form of higher drug prices.
    b. High U.S. drug prices pose financial hardship to patients and limit many patients' access to needed therapy.
    c. If – contrary to much evidence – gifts from drug companies do not influence physicians' selection of therapy, then many billions of patient dollars are being wasted.
    d. The acceptance of samples has been shown to influence physicians' prescribing behavior toward practices that are neither evidence-based, nor cost-efficient, nor clinically efficacious.[xix]
3. Erosion of the physician-patient relationship
    a. The perception that physicians are indebted to industry may cause patients to lose trust in their physicians' commitment to patient advocacy.[xx,xxi]
    b. The publicity criterion: physicians should be willing to disclose their gifts to their patients.
4. Self-protection: refraining from accepting gifts (typically quid pro quo arrangements to prescribe drugs in exchange for payment, often in the context of a "study") may protect physicians from prosecution under federal anti-kickback regulations.[xxii]

The PhRMA Code

The Pharmaceutical Research & Manufacturing Association developed a "Code on Interactions with Healthcare Professionals" that took effect in July 2002. The code[xxiii] contains the following provisions, here summarized briefly.

1. Relationships should "benefit patients" and "enhance the practice of medicine."

2. Informational presentations may be accompanied by occasional "modest" meals but no entertainment or recreational events.
3. Educational Events
    a. Financial support should go to the event sponsor, not to individual attendees.
    b. Modest meals may be supported.
    c. The primary objective of the event must be educational.
4. Reasonable compensation may be provided for bona fide (not token) consulting services.
5. Financial assistance may be provided to allow professionals in training to attend "carefully selected educational conferences."
6. Educational items valued at less than $100 and "reminder items" may be offered.
7. Personal items and cash or cash equivalents should not be offered.
8. No "quid pro quo" gifts.

The PhRMA Code, while a welcome (if long overdue) guide for industry conduct, contains numerous loopholes large enough to admit sizable long-haul conveyances. It has no effect on the extremely biased nature of the information presented to doctors by drug company detail representatives. The characterization of meals provided at "educational events" sponsored by drug companies as "modest" would astonish people of "modest" means. The Code completely ignores the biased nature of information presented by sponsored speakers at many educational meetings for hospital medical staffs and local medical societies. The limitation of $100 in value for gifts is unlikely to have a significant effect on the feeling of indebtedness incurred through their acceptance by physicians.

Remember the invitation you received as a "regional opinion leader" in your specialty to attend a meeting over a long weekend at a luxurious resort to provide "consultation" to a drug company about its products? (Promoted as your opportunity to influence the company's future directions in research and development, such meetings really are designed to help the industry refine its marketing techniques and to curry favor with "opinion leaders," who will then return to their home institutions and promote the products they've been talking and hearing about.) Under the new PhRMA Code, the stream of such invitations flows unabated. No, they won't give you first class tickets now, and if you want to bring your spouse the extra airfare is on you. But there will be no charge for your guest to attend meals and receptions, none of which will meet anyone's definition of "modest."

The Social Science Perspective

Dana and Lowenstein have outlined the social science perspective[xxiv] on the conflicts of interests inherent in the relationships between physicians and the pharmaceutical industry. The authors show how the conventional wisdom on accepting gifts, "that physicians who are biased by the prospect of personal gains are [deliberately choosing] to do something unethical" – which, in turn, accounts for many physicians' indignant response to the suggestion that gifts create bias – is contrary to the findings of social science research. They describe a fascinating series of controlled experiments that demonstrate the powerful effects of *unintentional*, self-serving bias. They note that "small gifts may be surprisingly influential" by "subtly affecting the way the receiver evaluates claims made by the gift giver." What is more, physicians "are generally unaware of the bias, so they do not make efforts to correct for it…."

The experimental work they cite has important implications for policies adopted by professional organizations, institutions, and individual physicians. "The finding that individuals are not aware of their bias, *even when taught about it*, suggests that the problem cannot be dealt with effectively through training." [Emphasis added.] Furthermore, the experiments involving "small stakes" – paralleling small gifts – suggest that "a policy of limiting gift size is unlikely to eliminate bias." One of the authors' conclusions is that "[t]he implication for industry gifts is straightforward: they should be prohibited."

Conclusion

The development of guidelines by professional societies and the adoption of a code by the pharmaceutical industry are certainly positive steps toward an appropriate approach to gifts from the pharmaceutical industry. But many physicians continue to believe that interactions between physicians and the biomedical industry, and the

bestowing of gifts upon physicians by industry representatives, remain troubling influences that affect physician behavior in ways that do not benefit – and may even harm – patients by causing physicians to practice in ways that are inconsistent with the best available clinical evidence.

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