

Gifts to Emergency Physicians from the Biomedical Industry: Ethics and Policies

Policy Resource and Education Paper (PREP)

This policy resource and education paper (PREP) is an explication of the policy statement
“Gifts to Emergency Physicians from Industry”

Introduction

Over the past five decades, the landscape of interaction between physicians and biomedical industry representatives has shifted. As of the 1980s, few commentators and a limited number of studies had been published regarding the effects of gifts and interactions with the biomedical industry on physician decision-making. As we enter the 2020s, virtually every medical professional society, medical school, hospital system, and many individual medical practices, have a policy governing physician interactions with industry.¹

Gifts from industry have historically taken many forms, ranging from pens to reference textbooks to food provided to emergency department (ED) staff during shifts and “educational” dinners at local country clubs and high-end restaurants. While most emergency physicians agree that certain gifts are unethical, there is continuing debate regarding sponsorship of educational events as well as gifts that clearly benefit patients, such as starter pack coupons for expensive medications (eg, direct oral anticoagulants). This policy resource and education paper (PREP) will focus on the continuing ethical debates regarding gifts from the biomedical industry to emergency physicians, including a review of recent literature and of policies adopted by medical professional organizations.

In 2001, United States (US) industry expenditures for marketing of drugs and devices were estimated to be \$21 billion, with 84% of that total going toward influencing doctors. Before the industry’s chief lobbying group, Pharmaceutical Research and Manufacturers of America (PhRMA), made changes in its marketing guidelines in 2002, the open use of gifts and money to influence doctors was considered standard practice.² In the intervening years, there have been significant changes in how pharmaceutical and medical device companies interact with physicians and other medical professionals. Despite those changes, however, by 2016, it was estimated that spending for medical marketing had increased to \$30 billion, with \$20 billion directed towards physicians and other medical professionals. It is clear that these companies still value marketing to health care professionals.³

In March 2010, Congress weighed in on industry payments and gifts to physicians with provisions in the Patient Protection and Affordable Care Act (ACA). The ACA created a system of requirements for greater transparency regarding physician-industry relations. Its “Sunshine Act” provisions require biomedical industries to report any gift or payment to an individual physician that is valued at greater than \$10. This information is then made available in an open access website.

Ethical Considerations

A major argument in support of accepting gifts from industry is that this practice can benefit both physicians and patients. Industry representatives assert that they provide valuable information on new medications and devices and on new uses for existing products. This claim can be challenged in several ways, however. Acknowledging that physician learning is important, is it necessary for a physician to receive a gift, such as a free lunch, in order for this information to be shared? Industry representatives have a primary purpose of persuading physicians to use their products. In order to do this most effectively, they may provide biased information, withhold information on a competing product that is more effective or less expensive, or purposefully not mention negative studies regarding their own products. Physicians can attempt to interact with multiple industry representatives to avoid relying on a single perspective, but many therapeutic options, especially the least expensive ones, don't have representatives touting their products.⁴

The biomedical industry also supports physician education with grants for sponsored conferences. Physician groups and industry have established regulations for these grants, so that there is not a direct gift or remuneration to any specific physician. Since there is no direct gift, sponsorship in this manner is seen as less problematic.

Other gifts that are generally accepted are ones that primarily benefit patients. Examples include patient information sheets and anatomical models that can assist in patient education. Although these are given to physicians, their purpose is to benefit patients by helping them understand their conditions and treatments.

Lastly, some consider drug samples and starter packs of medications as gifts to physicians and a benefit to patients. The medications supplied are typically newer and more expensive than previous treatments, so patients can at least temporarily benefit from the samples. A current example is a direct oral anticoagulant coupon providing a month of free medication. This allows some patients to be discharged from the ED with therapy that may have required hospitalization or prior authorization in the past. The acceptance of samples has, however, been shown to influence physicians' prescribing behavior toward practices that are not evidence-based, cost-effective, or clinically efficacious.^{5,6}

In addition to arguments based on beneficial consequences of industry gifts to clinicians, commentators have advanced arguments based on respect for physician autonomy. These arguments assert that, as moral agents, physicians should be free to associate with whomever they choose, including industry representatives. As autonomous agents, physicians may give and receive gifts and enter into formal and informal business arrangements.

Social Science Perspectives

Many physicians view gifts from industry as a fringe benefit or perquisite of their medical practice and argue that gifts, especially small ones, do not bias their clinical judgment. Research has suggested otherwise, however.

Early research on gift-giving by Mauss in his 1925 book The Gift challenges the claim that gifts have no influence on physician practice choices. Mauss posits that gifts lead to reciprocal exchanges or, at minimum, an expectation of reciprocity. His basic research question became "*What power resides in the object given that causes its recipient to pay it back?*"⁷

In a 2013 study, Sah and Fugh-Berman found that "Professionalism offers little protection; even the most conscious and genuine commitment to ethical behavior cannot eliminate unintentional, subconscious

bias.” These investigators argue that physicians and other prescribers should be made aware of their susceptibility to influence. They suggest a change to social norms concerning gift giving by industry that makes accepting gifts “shameful” and links academic success directly to the level of lowest interaction and influence by the pharmaceutical and device manufacturing industry.⁸

A recent study by Georgetown University investigators could not definitively establish a cause-and-effect relationship between a physician receiving industry gifts and any subsequent upturn in prescribing. The study, however, had findings that linked gifts received to increased prescription writing. The authors point out that gifts are important: “Gifts, no matter their size, have a powerful effect on human relationships. Reciprocity is a strong guiding principle of human interaction. Even gifts of small value, such as “modest” industry-sponsored lunches, may foster a subconscious obligation to reciprocate through changes in prescribing practices.”⁹

Here are some of this study’s major findings:

- Nearly 40 percent of prescribers received gifts ranging in value from \$7 to \$200,000 (2013 gift total = \$3.9 million of meals, trips, honoraria, and other gifts).
- Gift recipients wrote more prescriptions than non-gift recipients (892 vs. 389).
- Gift recipients prescribed 7.8 percent more brand name drugs than those who did not receive gifts.
- Prescribers receiving smaller gifts (under \$500/year) issued both more prescriptions (30% vs 26%) and more expensive ones (\$114 vs \$85).
- Prescribers receiving larger gifts (over \$500/year) had the highest average prescription cost (\$189) and percentage of brand-name prescriptions (40%).⁹

In 2016, DeJong, et al, showed that even small gifts had a significant effect on prescribing practices. This study found that a meal with a value of just \$12-18 increased the prescribing of branded statins, beta-blockers, ACE inhibitors, and antidepressants.¹⁰

Investigators have also examined the effects of gift giving in government and business transactions outside of health care. The major conclusion was that the line between a gift and a bribe was thin, especially when the gift was given from a business to an individual or small group.¹¹

In summary, studies suggest that even gifts of minimal value create feelings of goodwill and indebtedness that do, in turn, influence choices of therapy. Physicians may believe that they are immune from such “advertising,” but that opinion is not consistent with studies of physician behavior.^{4,12,13} Physicians should instead be aware that any gift given by industry can affect their judgement, consciously or not, and they should also consider how their patients perceive their acceptance of gifts from industry.

In addition to the ethical issue of compromised objectivity in treatment, gifts to physicians have financial implications and other effects on the patient-physician relationship. The cost of gifts to physicians, free samples, and conference sponsorship may result in higher prices being passed on to the consumer. Whether this cost to industry is recouped by increased prescribing, and whether the prescribing that is influenced by gifts is appropriate, is complicated and unknown.

Gifts from industry may compromise the therapeutic relationship in yet another way. The perception that physicians are indebted to industry may cause patients to question whether their physicians are unbiased advocates for their best interests, both medically and financially.¹⁴⁻¹⁷ A 2011 study concluded that patients who were aware that their doctors received gifts from industry had lower levels of trust in their doctor and higher distrust of the health care system. The authors state that “greater efforts to limit industry-physician gifts could have positive effects beyond reducing influences on physician behavior.”¹⁶ The Sunshine Act

addresses this issue by making information about payments and gifts to physicians readily available. Such information may help patients assess whether their physician is able to provide unbiased treatment recommendations in the patient's best interest.

The following sections will examine responses from medical professional societies and biomedical industry trade associations regarding gifts to physicians.

Medical Society Recommendations

The American Medical Student Association (AMSA) was an early adopter of policies opposing gifts to physicians and medical students from the pharmaceutical industry. An AMSA statement adopted in 2002 “urges all physicians, residents, and medical students not to accept as end recipients any promotional gifts from the pharmaceutical industry.”¹⁸

In 2007, AMSA released a scorecard that publicly graded medical school policies on conflicts of interest. The scorecard measured policies on industry-funded gifts, meals, educational events, site access for sales reps, and conflict-of-interest disclosure requirements. The original scorecard was used annually from 2008 to 2013 and updated with more stringent criteria in 2014. Medical schools' grades improved over the years the scorecard was used. AMSA addressed the issue of free meals in a statement adopted in 2011 that “encourages all hospitals and residency programs to discontinue the practice of hosting industry-sponsored meals and lectures.”¹⁸

Emergency medicine residency programs, unlike medical schools, had no graded scorecards to examine potential conflicts of interest posed by gifts from industry. Guidance from the Council of Residency Directors in Emergency Medicine (CORD) in regard to this is vague, but it does refer to Accreditation Council for Graduate Medical Education (ACGME) guidelines. The following position statement was reaffirmed in 2017: “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. 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. 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.”¹⁹

The ACGME has a strong stance against gifts to physicians from industry. Some of its examples of inappropriate relationships with industry are:

- “drug lunches” with obvious promotional intent
- industry-sponsored lectures with little or no attention to negative results of clinical trials
- social functions attached to “information sessions” having a clearer marketing objective than scientific purpose
- promotional activity in which residents or medical students receive slides, lecture materials, and honoraria, and subsequently act as “experts,” delivering the packaged information at continuing medical education events.²⁰

An Association of American Medical Colleges task force also created strong guidelines on gifts to physicians from industry in 2008. These guidelines recommend that “academic medical centers should establish and implement policies that prohibit the acceptance of any gifts from industry by physicians and other faculty, staff, students, and trainees of academic medical centers, whether on-site or off-site.” This prohibition includes gifts that serve the purpose of professional or patient education. Regarding meals,

they recommend that “with the exception of food provided in connection with ACCME-accredited programming and in compliance with ACCME guidelines, institutions should establish and implement policies stating that industry-supplied food and meals are considered personal gifts and will not be permitted or accepted within academic medical centers,” and that policies should make clear that the same standard of behavior should be met off-site.²¹

The Emergency Medicine Residents’ Association (EMRA) reaffirmed its policy on receiving gifts in 2018. EMRA’s guidance to residents includes the following:

- Gifts should be related to education and training.
- No direct compensation should be accepted.
- Financial stipends should be administered through the residency program.
- No gift should be excessive, nor should it require a reciprocal responsibility which impacts patients.²²

The 2012 Ethics Curriculum Module of the Society of Academic Emergency Medicine (SAEM) includes general guidelines but few specifics regarding gifts from industry. SAEM, like CODA, focuses on the importance of educating students and residents about potential conflicts of interest when interacting with industry representatives. In regard to the specific issue of receiving gifts, it cites the American Medical Association’s (AMA) stance in 2011 that gifts accepted by physicians should primarily benefit patients and not be of substantial monetary value.²³

The American Academy of Emergency Medicine also advises its members to follow the AMA Code of Medical Ethics and has no other policy on gifts from industry.²⁴

The AMA Code of Medical Ethics Opinion 9.6.2 includes the following statement: “To preserve the trust that is fundamental to the patient-physician relationship and public confidence in the profession, physicians should:

- Decline cash gifts in any amount from an entity that has a direct interest in physicians’ treatment recommendations.
- Decline any gifts for which reciprocity is expected or implied.
- Accept an in-kind gift for the physician’s practice only when the gift:
 - will directly benefit patients, including patient education
 - is of minimal value.”²⁵

The American Osteopathic Association (AOA) offers the following limited guidance: “Gifts should be appropriate to patient care or the practice of medicine.” There are no specific AOA statements in regard to meals or the monetary value of gifts.²⁶

The American Academy of Pediatrics (AAP) last updated its industry gift guidelines in 2011. The AAP endorses the AMA guidelines, and it also permits acceptance of individual gifts of minimal value related to a “physician’s work,” such as pens and notepads.²⁷

The American College of Physicians (ACP) takes a stronger stance against gifts, acknowledging that “even small gifts can affect clinical judgment and heighten the perception and/or reality of a conflict of interest.” The ACP therefore “strongly discourages” the acceptance of a gift that might diminish, or appear to others to diminish, the objectivity of professional judgment.²⁸

The American Academy of Family Physicians has no specific guidance, but refers to the AMA Principles of Medical Ethics.

The Committee on Ethics of the American College of Obstetricians and Gynecologists (ACOG) published a Committee Opinion entitled “Professional Relationships with Industry” in 2008, and reaffirmed that Opinion in 2020. The ACOG Opinion includes the following statement: “Physicians should understand that gifts tied to promotional information, even small gifts and meals, are designed to influence their behavior. The acceptance of any gift, even of nominal value, tied to promotional information is strongly discouraged.”²⁹

The Council of Medical Specialty Societies (CMSS) created a “Code for Interactions with Companies” for its member medical specialty societies, including ACEP, in 2015. Regarding exhibitor gifts to physicians at member society meetings and educational conferences, the CMSS Code states that exhibitor gifts should be educational (for physicians or patients) and modest in value. The language for this Code reflects standards adopted by AMA, PhRMA, and the Advanced Medical Technology Association (AdvaMed).³⁰

In the face of increasing scrutiny, PhRMA developed a “Code on Interactions with Healthcare Professionals” that took effect in 2002 and has since been updated in 2009 and most recently revised in 2019. The Code allows meals for healthcare professionals and their staff as long as they are accompanied by presentations providing scientific or educational value. These presentations must be provided in a manner conducive to informational communication, the meals must be modest as judged by local standards, and they are limited to the in-office or in-hospital setting. Spouses or friends not on staff are prohibited from attending these meals. Also, “take-out” meals or meals to be eaten without a company representative being present are not appropriate.

The PhRMA Code also prohibits the distribution of non-educational items, including pens, note pads, mugs, and similar “reminder” items with company or product logos. It does allow items designed primarily for the education of patients or health care professionals if the items are not of substantial value (\$100 or less) and do not have value to health care professionals outside of their professional responsibilities.³¹

Whereas PhRMA represents research-based pharmaceutical and biotechnology companies, AdvaMed represents companies that develop, produce, and market medical technologies. AdvaMed developed its own Code of Ethics on Interactions with U.S. Health Care Professionals in 1993, updated it in 2003, and revised it again in 2009.

Like PhRMA, AdvaMed allows educational meals where the meal is subordinate in time and in focus to the presentation of scientific information. AdvaMed does, however, allow these meals to be at other locations, such as restaurants, as long as the venue is deemed conducive to learning. All of the other limitations to the meals are similar to the PhRMA Code. AdvaMed also prohibits non-educational “reminder” items and allows inexpensive educational items, but it permits some educational items, such as textbooks and anatomical models, that cost more than \$100. The AdvaMed Code also allows companies to provide “reasonable quantities” of products at no charge to permit health care professionals to evaluate a product or educate patients about a product and its use. Unlike PhRMA, AdvaMed allows companies to pay for travel and lodging under certain circumstances, such as when health care professionals need to be brought together to deliver training and education concerning medical technologies. Both PhRMA and AdvaMed prohibit providing entertainment or recreation to health care professionals in any form.³²

As noted above, the Open Payments Program, originally known as the “Sunshine Act,” is a federal program intended to disclose the financial relationships between health care professionals and teaching hospitals, on the one hand, and the pharmaceutical and medical technology industries, on the other. Group

purchasing organizations (GPOs) are also included as reporting entities, and all are required to submit the following to the federal database:

1. Certain payments and other transfers of value to health care professionals and teaching hospitals. These include:
 - a. Honoraria, gifts, and royalties
 - b. Consulting and speaking fees
 - c. Grants and research charitable contributions
 - d. Medical education programs
 - e. Space rental and facility fees
 - f. Debt forgiveness
 - g. Long-term medical supply or device loans
 - h. Acquisitions
2. Certain ownership interests held by health care professionals and their immediate family members
3. Transfers of value to healthcare professional owners

The threshold amount for reporting is adjusted based on the consumer price index. In 2013, the first year reporting was required, any payment or transfer of value less than \$10 was excluded from the reporting requirements. However, if the annual total amount exceeded \$100, reporting of all transfers of value was required. In 2020, the maximal amount allowed prior to reporting was \$11.04 with an annual maximum of \$110.40. Since 2013, Open Payments has reported \$53.06 billion in payments and 76.25 million total records from more than 2,000 companies. These payments were made to 1.08 million physicians and 1,300 teaching hospitals.³³

Conclusion

The medical association and industry policies surveyed in this article have adopted increasing restrictions on acceptance by physicians of promotional (branded) gifts that do not directly benefit patients. When considering whether to accept a gift that benefits patients, physicians should identify and weigh the ethical consequences of their decisions. Physicians should be free to interact with industry representatives if they choose, but should be cognizant of the behavior changes those relationships can cause. A good question is “Would you want your patients to know about this interaction?” Given the disclosures mandated by the Sunshine Act, it is possible they will! In summary, the compromised objectivity that even small gifts cause in prescribing patterns should cause emergency physicians to pause and reflect on the consequence of accepting them.

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