

Relationships with Pharmaceutical Representatives – Core Concepts

Outline: Review of the Literature

“Education aims to eradicate the belief that an individual is exempt from influence (17)” in terms of interactions with industry representatives.

Pharmaceutical Companies and Academic Departments of Psychiatry [1]

- It was recommended by Dr. Christensen in a 1998 article that residency training programs make an attempt to formally incorporate the topic of physician interactions with pharmaceutical representatives into ethics teaching curriculum and that each department consider the establishment of specific ground rules that would govern interactions.
- Although ethical guidelines exist, Dr. Christensen questioned how familiar psychiatry residents are with these specific directives.

Professionalism and Physician Interactions with Industry [2]

- Physicians have unique responsibilities based on the “fiduciary” nature of the patient-physician relationship and specified laws regarding healthcare.
- Physicians must protect the best interests of patients, with clinical decisions free of undue influence.
- This topic is so important that the ACGME has regulated it, and it is currently a requirement that any ethics curriculum include instruction in and discussion of published guidelines regarding gift giving to physicians [3].
- In a competitive trillion-dollar industry, sales personnel are finding creative strategies to “detail” physicians:
 - \$8000-\$13,000 per year is spent per physician
 - Pharmaceutical companies continue promotional practices because they see a positive “return on their investment”
 - A study has shown that physicians who accepted money from industry to attend conferences, speak at meetings, or participate in research projects were more likely to request that drugs be added to formularies [4].
 - Costs of industry-sponsored trips, meals, gifts, conferences, symposiums and honoraria, consulting fees, and research grants are added to the prices of drugs and devices [5].

Do you think that physicians who attend sponsored meetings or dinners are more likely to let these interactions bias them?

- Physicians typically report that they are not biased by financial arrangements with pharmaceutical companies, although there is a large body of research to suggest that they are [6].
 - Most physicians do not perceive themselves as biased.
 - Most physicians do admit that conflicts of interest might compromise **other** physicians’ decisions.
 - Bias is recognizable, but only in others!!!
 - Even small gifts, referred to as “reminder items” (pens, pads), affect physicians’ judgment toward products.
 - Even when individuals try to be objective, their judgments are subject to an unconscious and unintentional self-serving bias.
 - Individuals are generally unaware of the bias, so they do not make efforts to correct for it or to avoid the conflicts of interest in the first place.

Why is it important to be cognizant of the concept of being unaware of the bias present when interacting with industry representatives?

- A review of 29 articles showed that physician interactions with pharmaceutical companies led to increased prescription costs and non-rational prescribing [7].

Ethical Arguments in favor of and against accepting gifts are reviewed here [8].

<i>Arguments in favor of accepting gifts</i>	<i>Arguments against accepting gifts</i>
Physician autonomy: physicians should be free to associate with whomever they choose	Gifts create feelings of goodwill and indebtedness that do, in turn, influence choices of therapy (mostly unconsciously) for the wrong reasons
Samples provide access to drug therapy for indigent patients, convenience for others (benefit to patients)	Information from drug representatives is not reliable, since its primary purpose is to persuade physicians to use certain drugs
Industry representatives provide timely information on drug therapy to busy physicians (benefit to patients)	One study demonstrated a three-fold increase in the use of a particular drug following grand rounds sponsored by a pharmaceutical company [9]
Educational gifts and events increase physician knowledge and thereby improve patient care (benefit to patients)	The cost of gifts to physicians – including “free” samples – is ultimately borne by patients in the form of higher drug prices
Gifts provide clear benefits to physicians in an era of shrinking reimbursement	High U.S. drug prices pose financial hardship to patients and limit many patients’ access to needed therapy
Physicians may act to enhance their own interests provided that the interests of others are not significantly harmed	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
Educational benefit of sponsored conferences (particularly unrestricted educational grants)	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 [10]
Physicians can accept gifts from industry and still make unbiased clinical judgments about drug therapy. (we have found this is controversial, as studies show that there is bias even when we do not think there is [6])	The perception that physicians are indebted to industry may cause patients to lose trust in their physicians’ commitment to patient advocacy [11,12]
Interaction with multiple drug company representatives can prevent the potential bias of hearing only a single perspective.	The publicity criterion: physicians should be willing to disclose their gifts to their patients

	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 [13]
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Dangerous Liaisons: doctors-in-training and the pharmaceutical industry [14]

- Doctors-in-training are at a vulnerable stage of their careers, both in acquiring knowledge and forming lasting relationships
- Pharmaceutical companies create a sense of reciprocity, which may have adverse long-term consequences on attitudes, behaviors and patient care
- The pharmaceutical industry is an integral component of modern medicine and the medications produced by these organizations are essential in ensuring the best care for patients
- Advanced trainees are likely to be highly influenced by other professionals in the specialty, such as pharmaceutical representatives, because they are new to the field. As such, they are inherently more susceptible to the influence of any argument in favor of one medication over another as they have not yet had the opportunity to form sustained opinions of their own

Manipulation secondary to social science theory – “norm of reciprocity”

- There is a substantial body of evidence which suggests that, when a gift is received, individuals instinctively feel the need to repay in some form to relieve the sense of debt
- No overt request for reciprocation is required for a person to feel indebted [15]
- Theorists argue this is an evolutionary adaptation that enables humans to form trusting relationships whereby they can expect others to respond in kind to acts of giving [16]
- The natural tendency for reciprocity allows *opportunity for exploitation*
- By providing a gift or free service to an individual, companies can purposely work to create a sense of debt between the physician and the industry organization
- Pharmaceutical companies operate under this motive and have received criticism for this as they are *actively aiming to manipulate doctors*

Pharmaceutical industry exposure in our hospitals: the final frontier [17]

- Despite acknowledgement of study findings to the contrary, doctors commonly state that they are able to effectively manage pharmaceutical company representative interactions such that their own prescribing is not adversely impacted [18]
- In one study, whereas 51% of surveyed doctors agreed that pharmaceutical company representatives had a large influence on the doctors’ prescribing habits, only 1% believed that this influence applied to themselves [19]
- There is a shared belief amongst some doctors that a sponsored lunch at a work meeting, for example, is harmless and that a small exposure, be it a gift or a lunch, is unlikely to have significant impact on prescribing practices [20,21]
- Exposure to pharmaceutical products and branding is likely to affect an individual’s objectivity towards the brand, and his or her prescribing behavior in relation to associated products
- A 2010 systematic review showed that doctors’ exposure to pharmaceutical promotional material was associated with, on average, higher prescribing frequency, higher costs and lower prescribing quality [20]

Physicians-Pharmaceutical Sales Representatives Interactions and Conflict of Interest: Challenges and Solutions [22]

- The Sunshine Act of 2007, now a part of the Patient Protection and Affordable Care Act, mandates disclosure of payments and gifts to physicians
- Detailing Physicians: one on one marketing to physicians by pharmaceutical representatives. Representatives try to convince the physician how their company products are the best and need to be prescribed. Provides busy physicians up-to-date information about the pros and cons of using the promoted drugs and keeps them abreast with the cutting edge advances in the field in general.
- Using smart marketing strategies and tactics such as offering gifts, friendship, and flattery, representatives can influence physicians to prescribe their brand drugs in excess.
- While legitimate prescriptions are necessary and help patients, the profit incentives create an opportunity for misuse and conflict of interest leading to violation of medical ethics on the part of the physicians.
- Though very small amounts of gifts can sway the prescriber's patterns of practice [23,24], it is not clear where the minimum is or whether a total ban would even work at all [23]
- Studies related to the perception and attitudes of the physician show that most physicians deny that they are influenced by the promotional pitches of the pharmaceutical sales representatives [18,25,7], although there is evidence that physicians do admit that they are influenced [26,27]

Social Psychology Techniques in Marketing Strategy

- **Reciprocation:** a social rule that says people should repay, in kind, what another person has provided for them; that is, people give back (reciprocate) the kind of treatment they have received from another. By virtue of the rule of reciprocity, people are obligated to repay favors, gifts, invitations, etc. in the future [28,29]
 - **Commitment:** The rule of commitment is a type of social norm that is often used by marketers and salespeople to get consumers to make purchases. According to this norm, we typically feel obligated to follow through with something after we have made a public commitment. Once we've made some type open pledge to something, we feel both social pressure and internal psychological pressure to stick to it [30]
 - **Social Proof:** also known as **informational social influence**, is a psychological phenomenon where people assume the actions of others in an attempt to reflect correct behavior for a given situation. This effect is prominent in ambiguous social situations where people are unable to determine the appropriate mode of behavior, and is driven by the assumption that the surrounding people possess more knowledge about the situation [31]
 - **Liking:** Beyond similarity, another extremely powerful predictor of liking and attraction is our perception of another person's liking of us. We like to be liked, and just knowing that someone likes us is enough for us to feel attracted to that person [32]
 - **Scarcity:** in the area of social psychology, works much like scarcity in the area of economics. Simply put, humans place a higher value on an object that is scarce, and a lower value on those that are abundant [33,34]
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- Physicians are susceptible to influence because they are overworked, overwhelmed...and feel underappreciated...bearing food and gifts, drug representatives provide respite and sympathy [35]
 - Katz et al remark that food flattery and friendship are powerful tools of persuasion, more so when they are combined [23]
 - Studies show that pharmaceutical sales representatives downplay the information about safety and side effects and exaggerate benefits regarding their products [36,37]

The American Medical Association Working Group for the Communication of Ethical Guidelines on Gifts to Physicians from Industry [38]

Many gifts given to physicians by companies in the pharmaceutical, device, and medical equipment industries serve an important and socially beneficial function. For example, companies have long provided funds for educational seminars and conferences. However, there has been growing concern about certain gifts from industry to physicians. Some gifts that reflect customary practices of industry may not be consistent with the Principles of Medical Ethics. *To avoid the acceptance of inappropriate gifts, physicians should observe the following guidelines:*

[1] Any gifts accepted by physicians individually should primarily entail a benefit to patients and should not be of substantial value. Accordingly, textbooks, modest meals, and other gifts are appropriate if they serve a genuine educational function. Cash payments should not be accepted. The use of drug samples for personal or family use is permissible as long as these practices do not interfere with patient access to drug samples. It would not be acceptable for non-retired physicians to request free pharmaceuticals for personal use or use by family members.

[2] Individual gifts of minimal value are permissible as long as the gifts are related to the physician's work (e.g., pens and notepads).

[3] The Council on Ethical and Judicial Affairs defines a legitimate "conference" or "meeting" as any activity, held at an appropriate location, where (a) the gathering is primarily dedicated, in both time and effort, to promoting objective scientific and educational activities and discourse (one or more educational presentation(s) should be the highlight of the gathering), and (b) the main incentive for bringing attendees together is to further their knowledge on the topic(s) being presented. An appropriate disclosure of financial support or conflict of interest should be made.

[4] Subsidies to underwrite the costs of continuing medical education conferences or professional meetings can contribute to the improvement of patient care and therefore are permissible. Since the giving of a subsidy directly to a physician by a company's representative may create a relationship that could influence the use of the company's products, any subsidy should be accepted by the conference's sponsor who in turn can use the money to reduce the conference's registration fee. Payments to defray the costs of a conference should not be accepted directly from the company by the physicians attending the conference.

[5] Subsidies from industry should not be accepted directly or indirectly to pay for the costs of travel, lodging, or other personal expenses of physicians attending conferences or meetings, nor should subsidies be accepted to compensate for the physicians' time. Subsidies for hospitality should not be accepted outside of modest meals or social events held as a part of a conference or meeting. It is appropriate for faculty at conferences or meetings to accept reasonable honoraria and to accept reimbursement for reasonable travel, lodging, and meal expenses. It is also appropriate for consultants who provide genuine services to receive reasonable compensation and to accept reimbursement for reasonable travel, lodging, and meal expenses. Token consulting or advisory arrangements cannot be used to justify the compensation of physicians for their time or their travel, lodging, and other out-of-pocket expenses.

[6] Scholarship or other special funds to permit medical students, residents, and fellows to attend carefully selected educational conferences may be permissible as long as the selection of students,

residents, or fellows who will receive the funds is made by the academic or training institution. Carefully selected educational conferences are generally defined as the major educational, scientific or policy-making meetings of national, regional or specialty medical associations.

[7] No gifts should be accepted if there are strings attached. For example, physicians should not accept gifts if they are given in relation to the physician's prescribing practices. In addition, when companies underwrite medical conferences or lectures other than their own, responsibility for and control over the selection of content, faculty, educational methods, and materials should belong to the organizers of the conferences or lectures.

The Council of Ethical and Judicial Affairs (CEJA) operational guidelines on gifts to physicians from industry: an update [39]

1. The gift primarily benefits patients
2. The gift should not be of substantial value (defined by the AMA as more than \$100)
3. If the gift is an educational activity, it must be unbiased and legitimate (free of bias in content or selection of speaker)
4. No "strings" must be attached (gifts should not be contingent on physicians performing an activity specified by the company)

Case Vignette's will be covered in the second session of this module to illustrate and incorporate the AMA guidelines into real word situations and will be discussed afterwards so keep these guidelines in mind.

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