Physicians
and
the pharmaceutical industry:

a symbiotic relationship?

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Since physicians are the health professionals that primarily prescribe pharmaceutical products, physicians' prescription practices are critically important to the profits of the pharmaceutical industry. Similarly, the pharmaceutical industry can be important to physicians as a source of new product information for patient treatment. Given this potentially symbiotic relationship, there is a critical need for regulation of the interaction between industry and physicians. While governments do provide a legislative framework for such regulation, most detailed regulation is currently provided by the respective codes and guidelines of the physicians and the pharmaceutical industry. Since the scope of such self-regulation is very broad, this paper restricts itself to examining the issue of gift-giving, including drug samples.

Industry interaction with physicians

The interaction between physicians and the pharmaceutical industry can be viewed in terms of supply and demand. The pharmaceutical industry has the money, which it can supply to physicians in various forms such as promotional gifts, entertainment, free drug samples, and funding for continuing medical education. The physicians have a demand for continuing education in order to discharge their professional obligations to their patients. There is an overlap or duality of interest of both the pharmaceutical industry and physicians with respect to their encouragement of the effective and responsible use of drugs in treatment and care, the monitoring of their use, and the conduct of innovative research.

Notwithstanding this overlapping of interests, physicians and the pharmaceutical industry each have a different emphasis and they focus on different stakeholders. The pharmaceutical companies' principal emphasis is the encouragement of the use of their products; the physicians' primary emphasis is effective patient care. The primary stakeholder in patient care is the patient; while the principal stakeholder in industry is the shareholder (Komesaroff and Kerridge 2002). However, the

relationship between physicians and the pharmaceutical industry is often more complex, as each party may be influenced by a variety of different interests and stakeholders, e.g., community welfare.

It should not be assumed that where a duality of interest occurs between physicians and the pharmaceutical industry, there will always be a conflict of interest. Dualities of interest constitute “conflicts” only when they are associated with competing obligations that are likely to lead directly to a compromise of primary responsibilities (Komesaroff and Kerridge 2002).

One study suggested that if a physician has a relationship with a pharmaceutical company, he or she tends to prescribe more of its products (Komesaroff and Kerridge 2002). In itself, this is not evidence of wrongdoing by either party. There are many potential explanations as to why this occurs. A pharmaceutical company may inform a physician about a new product because this is the best product available for the treatment of certain of the physician’s patients. In this case, the relationship may result in a “win-win” situation. The pharmaceutical company incurs costs educating the physician about the new product, but may recoup these costs and make a profit on sales prescribed by the physician. The physician may obtain information he needs to give better care to some of his patients and they may benefit accordingly.

However, problems can and often do arise because the relationship between physician and pharmaceutical company is open to varying degrees of abuse. For example, the pharmaceutical company representative may practice selective disclosure when providing information. Without all the relevant information, the physician may not be able to adequately assess the suitability of the product for his patients’ use. This situation is complicated by the fact that every salesperson practices selective disclosure to some extent. It is often called “putting one’s best foot forward.” The difficulty lies in determining where one should draw the line.

Since the relationship between physicians and pharmaceutical companies is open to abuse in a myriad of ways, safeguards are necessary to reduce the chances of a duality of interest becoming a conflict of interest and corruption. Because abuses

have occurred in the past and because positive outcomes are usually not reported or are under-reported, there is a tendency for the public to label the relationship as "bad."

The fact that both physicians and the pharmaceutical industry have instituted codes of conduct governing their relationship is evidence of their concern about the public's perception of that relationship. The physicians do not want to give the appearance of this relationship biasing their independent, professional judgement, which underlies the integrity of their fiduciary relationship with their patients. The pharmaceutical companies do not wish to be cast as corrupting one of the last professions the public still trusts. Instead, they wish to reap whatever benefits can be had from being perceived as "good corporate citizens." This is particularly important in the current environment in which the pharmaceutical industry has been subject to increasing scrutiny by NGOs, the media, and researchers.

Consequently, both physicians and the pharmaceutical industry have respectively developed codes of conduct or guidelines to govern their members in this relationship. These codes and guidelines attempt to address such issues as advertising, gift giving, drug promotions, support for travel, meeting sponsorship and medical education activities, research, and consulting. In this paper, the author has chosen to discuss the issue of gift-giving, including drug samples.

Attempting to address abuses: codes, guidelines & policies

Physicians' codes, guidelines and policies on receiving gifts and drug samples

Various approaches to self-regulation have been taken by different physicians' organizations. However, a review of these approaches reveals general themes. In most cases, the primary justification for having a direct relationship between the pharmaceutical industry and individual physicians seems to be based on the premise that an advancement of patient healthcare will occur through increased education and research. This assumes that the information provided to the physician is impartial and also disregards the capacity of physicians to keep

themselves up to date about advances in drug therapy by way of medical and other academic journals.

For this reason, the AMA (American Medical Association) states, “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” (AMA 2004, Guideline 1). They also make the point that individual gifts of minimal value are permissible as long as these gifts are related to the physician’s work (Guideline 2), but that no gifts should be accepted which have strings attached (Guideline 7).

The ACP (American College of Physcians) *Ethics Manual* (1998) goes further by strongly discouraging the acceptance of gifts and hospitality from the healthcare industry. They argue that the acceptance of even small gifts has been documented to affect clinical judgement and heightens the perception (as well as the reality) of a conflict of interest. The *Ethics Manual* also states that while following the Royal College of Physicians’ guideline “Would I be willing to have this arrangement generally known?” physicians should also ask, “What would the public or my patients think of this arrangement?” (ACP 1998).

While emphasizing patient care, the general approach used by the CMA (Canadian Medical Association) policy on *Physicians and the Pharmaceutical Industry* (CMA 2001) is not inconsistent with that used by the AMA and the ACP. One of the general principles of the CMA policy requires the primary objective of interactions between physicians and industry to be the advancement of health of Canadians rather than the private good of physicians or industry. Another is that relationships with industry are appropriate only insofar as they do not negatively affect the fiduciary nature of the patient–physician relationship. The principles also instruct physicians to resolve any conflict of interest between themselves and their patients resulting from interactions with industry in favor of their patients. They specifically warn physicians to avoid any self-interest in their prescribing and referral practices (CMA 2001).

As outlined above, some professional organizations are more specific than others. However, the general theme appears to be that while minor gifts, entertainment, and drug samples should not be solicited they may be acceptable if they directly promote better patient care or indirectly promote education or research and, in either case, do not affect the integrity of the physician–patient relationship.

The pharmaceutical industry's codes of practice on gift-giving and drug samples

In the same way that the medical profession has recognized the need to provide its members with guidance on their relationship with the pharmaceutical industry, the pharmaceutical industry has realized that its employees need guidance as well. The industry is concerned that its employees may sully the pharmaceutical industry's reputation. The industry does not want their interactions with healthcare professionals to be perceived as inappropriate by patients or the public at large (PhRMA 2002). In order to avoid being overrun with the detailed nature of voluntary codes at the level of national associations, it is perhaps most instructive to start with the general principles contained in the IFPMA (International Federation of Pharmaceutical Manufacturers Associations) *Code of Pharmaceutical Marketing Practices* (IFPMA 2000).

The IFPMA, which has member associations in more than 55 countries, purports to represent the worldwide research-based pharmaceutical industry and the manufacturers of prescription medicines generally. The IFPMA's *Code of Pharmaceutical Marketing Practices* requires its terms to apply to any company belonging to at least one member association in all the countries of the world where that company operates. Companies entering into licensing and agency agreements are expected to require their licensees and agents to respect the provisions of the IFPMA Code.

The Code is intended to define universally applicable baseline standards of marketing practices. With respect to gift-giving and hospitality these are:

(1) Inappropriate financial benefits or material benefits, including inappropriate hospitality, should not be offered to healthcare professionals to influence them in

the prescription of pharmaceutical products.

(2) Promotional items of insignificant value, provided free of charge, are permissible as long as they are related to the healthcare provider's work and/or entail a benefit to patients.

(3) Text or reference books/information and other educational material may be given to healthcare providers if they serve a genuine educational function (IFPMA 2000, sec. IV).

With respect to drug samples, the only marketing practice stated is that samples, clearly identified as such, may be supplied to the prescribing professions to familiarize them with products, to enable them to gain experience with the product in their practice, or upon request.

For the purpose of self-discipline, there is a mechanism under which IFPMA deals with complaints of alleged breaches of the Code. When a complaint is received by the IFPMA Secretariat, a summary is required to be sent to the company that is the subject of the complaint, the member association where that company has its headquarters, and the member association (if any) of the country in which the alleged breach has occurred. The relevant member associations are asked to consult the company and report back to IFPMA the results of their investigation of the case. An IFPMA decision is communicated to the complainant, the company, and the respective member associations. Where it is determined that there has been a breach of the Code, information identifying the company concerned and the complainant is immediately made public. Status Reports on the IFPMA Code, summarizing all complaints received, are also required to be published periodically and given wide circulation to government health departments, WHO, the technical press and leading medical journals, and to member associations of IFPMA.

PhRMA (Pharmaceutical Research and Manufacturers of America) adopted its voluntary *PhRMA Code on Interactions with Healthcare Professionals* effective July 1, 2002. With respect to gifts, the Code concentrates on the end-use of gift items. Items primarily for the benefit of patients may be offered to healthcare professionals if they are not of substantial value (US$100 or less). Providing product samples for patient use in accordance with the Prescription Drug Marketing Act is acceptable.

Items of minimal value may be offered if they are primarily associated with a healthcare professional's practice (such as pens and similar reminder items bearing the company or product logo). Items intended for the personal benefit of healthcare professionals (such as sporting event tickets) should not be offered. Payments in cash or cash equivalents (such as gift certificates) should not be offered, except as compensation for *bona fide* services. Nothing should be offered or provided in a manner or on conditions that would interfere with the independence of a healthcare professional (PhRMA 2002).

One surprising omission in the PhRMA Code is a complaints procedure. Furthermore, with regard to enforcement of the Code, each member company is only strongly encouraged to adopt procedures to assure adherence to the Code (IFPMA 2000). Unlike many other national Codes of Practice, there is no mechanism for dealing with members who violate this domestic Code. This omission encourages the perception that the Code is not being vigorously enforced.

Canada's Research-Based Pharmaceutical Companies' (*Rx&D or CRBPC) Code of Marketing Practice* provides that member companies must not distribute service-oriented items or conduct "special promotions", which cannot be justified if subjected to scrutiny by members of the health professions and the public (CRBPC 2005). Acceptable service-oriented items are defined as items the primary goal of which is to enhance the healthcare practitioner's/patient's understanding of a condition or its treatment. When member companies provide hospitality, they must ensure that all hospitality is conducted within the limits of acceptable public and professional scrutiny, keeping in mind the need for an ethical relationship in any social interaction between healthcare professionals and pharmaceutical companies (CRBPC 2005). During such interactions, companies may provide participants with refreshments/meals that are modest in content and cost. In all instances, the provision of refreshments/meals must be clearly incidental. No other form of hospitality or entertainment is to be provided.

The Canadian Rx&D Code requires that samples (referred to as CEP (Clinical Evaluation Packages)) only be given to authorized healthcare practitioners who have filled out a request form for the CEP (CRBPC 2005, sec. 3.2.3(i)). However,

the Canadian Code goes on to specify that all free goods (CEPs) given to a healthcare practitioner as part of an order must be included on the invoice. If no order is made when the free goods are supplied, the goods must be documented on a separate no charge invoice (sec. 3.2.3(iv)). The Canadian Code does not require that samples be limited in number, but puts the emphasis on the healthcare practitioner by allowing the distribution of as many CEPs as the healthcare practitioner believes is required for the proper evaluation of clinical response (sec. 3.2.3(v)). Provisions for storage, disposal, and auditing of CEPs held by company representatives are also included (secs. 3.2.4, 3.2.5, and 3.2.6).

One striking difference between the PhRMA Code and the Canadian Code is the latter's inclusion of provisions for enforcement. The Rx&D Marketing Practices Committee reviews complaints and can publish infractions and impose fines (sec. 15.2). There is also a right of appeal to an arbitrator selected and agreed to by the two parties involved in the complaint or, failing agreement, one appointed by the Chairman of the Board of Rx&D (sec.15.4). The decision of the arbitrator is final and the company in question must adhere to the decision as a condition of continued membership in the association (sec. 15.6).

Conclusion

In this chapter, the need to regulate physician–industry interaction has been identified. The goal of such regulation is to ensure that prescription patterns are based on the real health needs of the patient rather than industry influence. More explicitly, excerpts have been reviewed from a select number of codes offered by professional medical associations and the pharmaceutical industry as a means to regulate themselves. How can one test the efficacy of the self-regulatory regimes that these two groups have established?

The Nolan Committee on Public Standards (1995) in the United Kingdom suggested that there are seven relevant principles applying to all aspects of public life. The relationship between physicians and the pharmaceutical industry also involves duties owed to the public. Accordingly, the author used the seven Nolan Committee principles as the starting point for drafting the amended but

corresponding principles described below, which are specifically applicable to the relationship between physicians and the pharmaceutical industry. To test the efficacy of the professional medical associations' and pharmaceutical industry's self-regulatory regimes, one should ask whether or not these principles are being applied to the interaction between members of their respective organizations.

Selflessness: Physicians have a duty to act in the best interests of their patients. Pharmaceutical companies have a duty not only to their shareholders, but also to the community at large. To fulfill their duty to the community, pharmaceutical companies must operate within the confines of socially acceptable behavior or risk loss of reputation, public boycotts, or legislative action. Socially unacceptable behavior by a company can ultimately lead to loss of business and become a failure in its duty to its shareholders. Both the physicians and the pharmaceutical companies or their employees must not compromise these public duties in order to gain financial or other material benefits for themselves, their families or their friends.

Integrity: Members or employees of both groups should not allow any physician to be placed in a position where he or she is under any financial or other obligation to a pharmaceutical company or its representative that might or might appear to improperly influence that physician in the performance of his or her medical duties.

Objectivity: Members or employees of both groups should strive to ensure that physicians in carrying out their medical duties, including entering into contracts with pharmaceutical companies, are able to makes choices based on scientific merit.

Accountability: Both physicians and national and international pharmaceutical industry organizations owe a duty to the public and must, through their respective organizations, provide for appropriate public scrutiny and discipline where necessary. They should also provide for appeals to qualified independent adjudicators.

Transparency: The organizations representing both groups should be as open and transparent as possible about all the decisions and actions they take. They should give reasons for their decisions and restrict information only when the wider public interest clearly demands (e.g., physician–patient privilege).

Honesty: Both physicians and employees of pharmaceutical companies should

be considered to have a duty to resolve any conflicts of interest arising from their interaction in a way that protects the public interest.

Leadership: Both physicians and pharmaceutical company executives should promote and support these principles by leadership and example (available at Committee on Standards in Public Life (CSPL) 2005).

While existing codes and guidelines can certainly be improved, an environment of integrity still seems to be elusive. The current negative perception of the existing relationship between the pharmaceutical industry and physicians suggests that something further is required. The best code of ethics is worthless unless it is both enforced and seen to be enforced. In order to reap the benefits of such enforcement, an organization must deal with enforcement in a transparent manner. A recent case involving AstraZeneca Canada Inc., one of Canada's largest drug companies, provides an interesting case study.

In a private letter addressed to the Chief Executive Officers of Rx&D's member firms, the Rx&D's president stated: "It is my obligation to inform you of a serious situation regarding one of our member companies, and of the industry as a whole, as a result of repeated non-compliance with the code of conduct. AstraZeneca Canada Inc. has reached an unprecedented number of infractions recorded in a second consecutive 12-month period" (Blackwell 2005). The company was put on six months' probation and a Rx&D spokesperson later stated that if it did violate the code again while on probation, it could be expelled. The organization also ordered AstraZeneca to communicate the action to healthcare professionals involved in the infractions and requested its CEO to appear before the Rx&D's board. No such measures have ever been taken before according to a Rx&D spokesperson (Blackwell 2005).

While these unprecedented actions are commendable in themselves, they are still less than what the public has a right to expect. One wonders why AstraZeneca wasn't put on probation after the first 12-month period? Why weren't such measures taken earlier? Why didn't Rx&D publicly announce the action it was taking, instead of only responding to later media reports? Why aren't all infractions and enforcement responses the subject of Rx&D press releases?

These omissions undermine the industry's credibility to regulate itself. An spokesperson said: "We are sending out a clear message … There will be no tolerance of non-compliance. This is serious" (Blackwell 2005). However, pharmaceutical industry organizations must not only "talk the talk", but "walk the walk". Strong leadership is necessary to achieve adequate transparency and to take effective action against industry members, when and where necessary. To do otherwise is to encourage the public's belief that pharmaceutical companies are conspiring to protect themselves at the public's expense. If this belief becomes strong enough, there will be great pressure to replace the self-regulatory regime with mandatory legislation. Such pressure can best be countered by bringing light through transparency to the enforcement process.

A symbiotic relationship has been defined as a "mutually advantageous" relationship (Barber 1998). To achieve a truly symbiotic relationship between physicians and the pharmaceutical industry, the light of transparency is required to dispel the darkness where conflict of interest, conspiracy, and corruption can thrive.

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This article was originally published as Chapter 5, at page 57, in "*The Power of Pills: Social, Ethical and Legal Issues in Drug Development, Marketing and Pricing'*, edited by Jillian Clare Cohen, Patricia Illingworth and Udo Schuklenk (Pluto Press, 2006). Copies of the book can be ordered from http://www.plutobooks.com/cgi-local/nplutobrows.pl?chkisbn=9780745324029