Health Care and the Drug Industry

Part I ~ Physicians: Prescribing Under the Influence?

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s difficult as it might be to believe, there actually was a time when driving under the influence of alcohol was socially acceptable. Now we are more than fully aware of the potential for injury to others, and not only is it unacceptable to do so, it is also illegal. Throughout the years the potential for injury and death from prescription drugs has also been demonstrated time and time again. One only has to go to the World Health Organization website to find countless recent examples of the risks and dangers of prescription drug use. 1 This is not to say that medications do not have their rightful place in medicine. They do, and they have provided modern medicine with some impressive accolades in treating disease and illness. However they can have significant health risks and it is in the best interest of prescribing physicians and of the patients they treat that these risks be minimized. Unfortunately, gift giving relationships between the drug industry and physicians have made it very difficult for the public to consistently receive the safest and most appropriate advice regarding their health and treatments for their disease.

What do you mean by gifts?

In today's medical world, the giving of gifts from industry to physicians is common and pervasive. These gifts come in all shapes and sizes, from the small and inexpensive pen, coffee mug or notepad, to the lavish weekend conference in a warm, holiday hot spot. They can be of a more professional nature, such as drug samples, copies of research papers, reimbursements for referring patients to clinical trials or sponsorships for educational activities. However, they can also be of a more personal nature as well, such as when conferences have social events attached to them, or if these activities include travel expenses, golf balls, coffee makers, or other personal gifts. Physicians and the drug industry have become very adept at making the latter sound much like the former, and this line is often confused.

Occasionally these interactions result in criminal investigation. Drug giant GlaxoSmithKline was accused last year of using World Cup soccer tickets, cash, stereos, and holidays to bribe Italian and German doctors into prescribing their drugs. In June 2003,

Astra-Zeneca was required to pay a \$355 million settlement for their part in a scheme in which US doctors billed insurance providers for drugs provided free by the company. These represent some of the more flagrant abuses of the physician-industry relationship. However, as a Turkish pharmacology professor commented after describing a similar example: "This is just the tip of the iceberg." I cannot help but wonder whether or not the first person to walk through the door in my new medical practice will in fact be a patient or a drug rep.

Why are they given?

In the drug industry, as in most other commercial endeavors, gifts are primarily designed to foster familiarity and recognition of a company's product, and drug names are often seen on notepads, pens, clocks, coffee mugs, and other trinkets which saturate the typical medical office. Gift giving also forms the beginnings of a social contract in which some form of reciprocity is desired, or even expected. In many cases this may or may not be outwardly expressed, but it has been consistently demonstrated in social science research that "the obligation to directly reciprocate, whether or not the recipient is conscious of it, tends to influence behaviour." In medicine, "the reciprocity rule is often exploited in that the giver (ie: drug rep) is not only able to decide the form of the initial favour, but also the form of the return favour as well. In other words, if physicians are to reciprocate for small gifts, they cannot do so in any form they please, as they are essentially compelled to reciprocate by supporting their benefactor's products."³

The drug industry also gives gifts to physicians because it provides a 'foot in the door' and an opportunity to pitch their latest drug. Industry often claims that such gifts are necessary to compensate physicians for their time, and the information they present is crucial in providing both the physician with the most up to date information, and the patient with the latest treatment technologies. Sales reps are trained specifically to capture the attention of the physician during the critical first few seconds of an interaction, and using gifts is a clever way of keeping their attention

for the next few minutes. In fact, former Pfizer Pharmaceuticals president G. Leubach was quoted as saying that marketing "is almost as scientific as anything we do."⁴

Why are they accepted?

If gifts to physicians are such an incredibly effective marketing strategy, then why is it we accept them? There can be no question that many physicians feel as though it is their professional privilege to accept them; that being part of the medical profession has given them an unalienable right to enjoy certain privileges, and gifts from the drug industry are merely a part of this right. Frequently these privileges involve financial rewards for signing patients on to drug research studies, and with each study physicians can earn up to \$20,000 per patient.⁵ Some doctors feel that the amount of work they do for the given study warrants this kind of remuneration. Others, like Dr. Douglas Kinsella, a retired assistant dean from the University of Calgary feel it to be excessive. Kinsella is particularly concerned with a growing number of physicians who are accepting financial remuneration and running their clinical trials "like a business." He adds: "The docs basically sign the forms and collect the cheques. The research nurses do most of the work."5

In many cases, physicians are pressured for time and complain about a lack of more objective research. The difficulty expressed by physicians in obtaining unbiased, objective information regarding the best treatments creates a void that the drug industry is very willing to fill. This void, real or not, often facilitates the transmission of biased information about the drugs they manufacture.⁶

For medical students, physicians act as mentors and role models, and are tremendously important. Many students are 'socialized' into accepting gifts because they see their mentors doing it, and assume it to be a part of what it means to be a physician. In some cases, the drug industry gift has been passed through, and subsequently endorsed by their medical school, as is the case for certain 'educational' materials. instances, the school may choose to avoid dealing with the issue and instead leave it up to the student to decide whether or not it is a problem. The problem with this is most students are unaware of the implications of their actions, yet at the same time they immediately recognize the increasing acceptance and responsibility they are being given as future doctors. disappointing and unfortunate as it is, accepting gifts often makes the student feel more like 'part of the team.'

Ultimately, there are many reasons why physicians and medical students continue to accept gifts from the drug industry, but whatever the reason, it is clear that most don't feel receiving them presents much of a

problem.⁷ This belief is often based on two things. First, there is a sense among many physicians that they are immune to any form of commercial influence. 8,9,10 Many will claim that whatever the drug industry throws at them, and whatever gifts they accept, nothing can sway their unaltered pursuit of what is best for their patients. The second reason for this belief is that if there is to be any influence motivated by the acceptance of gifts, it would clearly involve a conscious choice on the behalf of the physician. In other words, many think they would have to consciously decide to act on behalf of the gift giver. When asked about the influence of gifts from the drug industry, medical students also seem to think like physicians. One study found that 85% of medical students believe it is improper for politicians to accept a gift, whereas only 46% found it improper for them to accept a gift of similar value from a pharmaceutical company. 11 A more recent study of medical residents showed that 61% felt that "promotions don't influence my practice," while only 16% believed the same about other physicians' practices. 12 This evidence seems odd, and it is certainly unlikely that most physicians are unbiased and most other physicians are biased. Why is this so? Why is it that comprehensive research shows the more gifts a physician receives, the more likely he or she believes they don't influence their behaviour? 10,13 The answer to this question lies within the realm of social science, and in research on the social implications of gift giving and bias. It is here that one learns that not only is bias recognizable, but it is only recognizable in others. In other words, bias is subconscious and therefore physicians are unable to correct for it when making clinical decisions. 14

So what's the problem?

Many physicians have come to regard some form of gift giving as an integral part of their practice. For others it can be likened to eating a bowl of ice cream while on a restricted diet, or accepting that next drink when you know you'll pay for it tomorrow. You have a strange feeling to avoid it altogether, but it's so hard to resist. Plus, as one US physician describes: "The gifts provide a little fun." And if everyone else around you is doing it, then what's the problem?

Well, in the last twenty years or so, there has been increasing evidence that demonstrates why this is a problem. The most significant of these reasons is likely the irrefutable evidence that gift giving directly influences the behaviour of physicians in ways that benefit the drug industry. Perhaps the most recent comprehensive study, which reviewed the primary research of interactions between physicians and industry from 1994 to 1999, found mostly negative outcomes associated with the interaction. Physicians were influenced in three ways: "These included an

impact on knowledge (inability to identify wrong claims about medication), attitude (positive attitude toward pharmaceutical representatives; awareness, preference, and rapid prescription of a new drug), and behaviour (making formulary requests for medications that rarely held important advantages over existing ones; nonrational prescribing behaviour; increasing prescription rate; prescribing fewer generic but more expensive, newer medications at no demonstrated advantage.)"13 Even before 1994, studies were showing a positive correlation between the cost of physicians' treatment choices and their amount of contact with pharmaceutical company representatives. 16 In 1989 and 1993, reviews by Dr. Joel Lexchin, a Toronto emergency physician and faculty member at York University, demonstrated similar findings. 17,18 To illustrate the results of these studies consider the following from a faculty member of the USC School of Medicine:

In February 1998 a drug called Trovan (trovafloxacin) became available. Trovafloxacin is a quinolone antibiotic similar to ciprofloxacin (the drug that became famous during the anthrax scare) and several others. Trovafloxacin had some advantages over its predecessors for certain types of infections, but for most clinical indications its expected activity was similar to that of other quinolones. As soon as the drug became available, our hospital environment was flooded with Trovan trinkets such as pens, pads, calendars, and door magnets, which appeared everywhere physicians congregated in the hospital. I also noted that physicians began prescribing Trovan at an astonishing rate, not only for the small group of cases in which it might have been the preferred antibiotic but also for cases in which it was equivalent to other quinolones and even for cases in which non-quinolone alternatives were preferable. In June of that same year, the US FDA issued a public health advisory about Trovan related liver toxicity, which had not been apparent during premarketing studies. The advisory restricted Trovan use to a limited set of clinical circumstances. In short order, Trovan trinkets stopped coming and the drug faded into oblivion. But in that single year of Trovan's availability, the FDA estimated that 2.5 million patients had received it in the US. Surely all those patients did not suffer conditions mandating prescriptions for Trovan; rather, many of them received it because of extraordinary product recognition, facilitated in part by those ubiquitous Trovan-labelled objects. 19

The attitudes of medical students are also affected by these interactions. This was outlined in a study which found that "[drug] representatives who did not offer gifts or who seemed to lose interest when they discovered they were conversing with a student made particularly bad impressions; the students were skeptical of the representatives' social skills and the validity of the information they provided. Conversely, the representatives who conversed with the students or who gave them gifts were described as 'helpful' and as having 'good information.'"²⁰ While it may seem fitting to be critical of the representatives' social skills when they are being dismissive to a student, it is not fitting, and even alarming that conclusions are being made on the validity of their information based on the type of interaction. What is even more alarming is the association between the formation of these attitudes and whether or not a gift was being given.

A conflict of interest

Another main reason why gift giving is so problematic is that it constitutes a huge conflict of interest for both parties involved. A conflict of interest exists "when a primary ethical or professional interest clashes with financial self-interest." When physicians who have committed themselves to the interests of their patients make decisions that allow financial self-interest to supercede those of their patients, they are acting against their code of conduct. In effect, they are sacrificing the goals of their patient in order to further the goals of industry. Since bias is unconscious, it follows that the resulting conflict of interest between self and patient is left unrecognized, and consequently the physician's decisions are affected. If industry truly is motivated to meet the interests of patients then there should be no need for gifts, because both physicians and industry would stand to benefit from the interaction.3

Physicians are also faced with a conflict of interest when they are authors of clinical practice guidelines (CPG's). In 2002, a comprehensive study published in JAMA found 81% of authors of CPG's had at least some interaction with the drug industry. Results also showed that "59% had relationships with companies whose drugs were considered in the guideline they authored, and of these authors, 96% had relationships that predated the guideline creation process." The authors were concerned that financial conflict of interest for authors of CPG's not only have the potential to affect the authors practice but also an enormous number of physicians who follow the CPG recommendations.

The ethics say no

Apart from the issue of conflict of interest, there also arises the argument that gift giving between physicians and industry contravenes the ethics contained within the oath of practice. The first duty, which is to *do no harm*, should restrict physicians from accepting gifts because ultimately these gifts are paid for by the patient through

the cost of drugs. Any costs that are beyond the normal research, development and marketing costs are harming patients by adding to the cost of their care. It has even been argued that by accepting gifts, the physician is actually stealing from the patient. The duty of *fidelity* challenges the physician to avoid engaging in activities which place the needs of another party above that of the patient. In short, the patient comes first. By accepting gifts from the drug industry, a physician is entering into a relationship with industry, and in doing so has placed the needs of the drug industry into conflict with those of their patients. Another aspect to this is that patients are often unaware that there is a gift giving relationship between physician and industry. Since researchers have found physicians to be extremely reluctant in making these relationships known to their patients, they should consider that deception also violates the duty of fidelity. The duty of justice calls for physicians to allocate resources on the basis of need. With so many people in this world in need of the most basic necessities, physicians have a responsibility to avoid participating in activities which unfairly reallocate resources to themselves.²²

How do patients feel about gifts?

For physicians who are really looking to make a difference, the opinions of patients should be regarded as an excellent means to gain insight into how one can improve their practice. Often patients are aware that some minimal gifts are given, and their opinions regarding the acceptability of such gifts are directly related to their perceptions of possible effects on prescribing behaviours and costs.²³ Patients are also like physicians in that "what they might not know is that these inexpensive penlights and notepads might actually undermine physician objectivity in ways that conflict with their own medical and financial interests."3 When researchers attempt to find out just how patients feel about these relationships, they often have difficulty locating physicians willing to take part in the studies. This lack of willingness suggests that physicians are justifiably conflicted about this behaviour.

Continuing medical education, or 'education'?

For physicians, continuing medical education (CME) events form an essential part of maintaining and upgrading their skills, as well as upholding a license to practice medicine. With so many doctors in one place, all learning about various diseases and their potential treatments, it should come as no surprise that the drug industry is very eager to get involved in the process. In fact, throughout the years they have become so deeply involved in sponsoring CME events that it can often be difficult to tell whose voice is being heard, the physician's or industry's. For this reason, continuing medical education (CME) events are required to be

organized and run by independent bodies. This is done in an apparent attempt to separate the marketing interests of the drug industry from the educational interests of the physicians who attend them. However, as one may expect many of these so-called independent bodies are for-profit companies who pitch their educational services to large pharmaceutical companies with slogans like: "Putting the science of medicine to work for you. Preparing and building the market through professional education." To the physician the concept of education has a completely different meaning from that used by industry. In fact, CME planning information often informs organizers that financial support from pharmaceutical companies will depend, to a large degree, on the marketing potential the event offers them. In the world of business, education is synonymous with marketing, and for many companies the money that goes to CME events comes straight from the marketing budget of that company.

Free textbooks for students: Who pays?

For a medical student in debt from years of tuition, the idea of a free textbook can be a welcome bonus. However before accepting, students should first remember two important rules. First, students need to realize that nothing in life is free. A text book that is free now will eventually have a cost. How that cost will be paid is difficult to say, it may be a cost in how they run their practice, the quality of care they provide for their patient, or a cost to society as a whole. An example of this is a 'free' textbook given to medical students with an ad on the back cover for the nonsteroidal anti-inflammatory drug Vioxx (rofecoxib). The comfort and familiarity gained by the student for this drug might lead them to believe it is better than other NSAIDs, even though evidence has shown it to be no more effective than other, less expensive NSAIDs.²⁴ At \$4/tablet, Vioxx costs health care 20 times the amount of one 20¢ tablet of the generic NSAID ibuprofen. To make matters worse, Vioxx was actually shown by its manufacturer Merck to have a higher incidence of adverse side effects than another generic naproxen.²⁴ To think that as medical students we are protected from drug industry influence would be a tremendous oversight.

The second rule is to understand that when a drug company gives a textbook to a student, it is not doing so out of the goodness of its heart as the word 'free' and 'gift' might imply. The reality is the company is making a calculated and well-founded decision to 'invest' in their education because it is in its best interest to do so. Beginning a relationship with medical students through 'free' textbooks is an attempt to foster goodwill on behalf of the student toward the pharmaceutical company. Ultimately, if it is then able to do this, when the student becomes a physician they

will likely feel comfortable and open to meeting with drug reps, and ultimately become 'effective prescribers'. Medical students represent the key to a drug company's future financial success, and it serves them well to begin fostering this relationship as early as possible. In fact, some students are entering medical school already having established an attitude of friendship and trust towards the drug industry during their undergraduate years. This is fine so long as both parties are committed to the welfare and interest of the patient as their ultimate priority. Given the drug industry's ultimate objective is an ever-increasing profitability, it is unlikely that these relationships will truly yield a positive outcome with regard to the patient.

Conclusion: Under the influence

Gifts are given from industry to physicians primarily because it is profitable to do so. Drug companies compete fiercely with each other for a given 'disease market' and it pays big to have physicians prescribing your drugs. Drug companies know precisely how influential these gifts are, especially the small gifts. It is for this reason that many of the drug sales reps who use gift giving to further their sales are restricted from accepting gifts themselves.

Industry-physician relationships have indeed become too close, as San Diego psychiatrist Loren Mosher believes. In a letter dated December 4, 1998, the former chief of the Center for Studies for Schizophrenia at the National Institute of Mental Health resigned his 35-year membership in the American Psychiatric Association (APA) stating: "The major reason for this action is my belief that I am actually resigning from the American Psychopharmacological Association...Unfortunately, APA reflects reinforces, in word and deed, our drug dependant society...We condone and promote the widespread overuse and misuse of toxic chemicals that we know have serious long-term effects...At this point in history, in my view, psychiatry has been almost completely bought out by the drug companies...Psychiatric training reflects their influence as well; ie: the most important part of a resident curriculum is the art and quasi-science dealing drugs, ie: prescription writing."25

Physicians may in fact be the last stumbling block leading to a change in how the two sides interact. Several years ago, UBC's Dr. Bob Woollard, wrote in the Canadian Medical Association Journal: "If we can move beyond the defensive irritability so often demonstrated by physicians secure in the belief that they are immune to the influence of industry then we will have come far indeed."²⁶

For many drug reps, the current method of detailing new drugs often poses ethical and moral dilemmas. However, their role is non-negotiable if they wish to remain employed. We cannot blame the drug industry for ensuring it is as profitable as possible. Physicians on the other hand, have a choice in how they practice medicine. Dr. Brett of the USC School of Medicine insightfully suggests: "Surely we can create practice environments that don't look like advertising billboards for pharmaceutical companies. Surely we can do better than to have drug representatives tell us how to practice medicine. And surely we can buy our own pens and notebooks. Each of these goals can be accomplished if physicians and their professional organizations would finally wake up and recognize small gift giving for what it is: cheap and effective marketing." Haavi Morreim, a professor with the University of Tennessee's School of Medicine agrees: "Physicians need to avoid being naïve. They need to quit protesting that because they're scientists, marketing doesn't influence them. They need to understand that the pen and the golfing trip are not designed to buy their souls; these "perks" are designed to foster familiarity and comfort with the drugs and sometimes create a gift relationship and the gratitude that goes along with it. That makes them very effective marketing tools."²⁷

Medical students have a unique opportunity because they are at the forefront of what will constitute the medical practice of tomorrow. They have the power to bring about change from the very foundation of medicine. Perhaps this project will help students gain awareness and update their beliefs with regard to the effects of relationships between physicians and the drug industry. It is surely up to us to protect the integrity and value society bestows upon us as physicians and future physicians. It is also crucial for us to protect the integrity of the medical student's education and the objectivity of the physicians who practice, both for the benefit of the patient and for society as a whole. Let us move forward with the strength and conviction that is ours if we are ready to make a real and lasting difference in the healthcare of tomorrow.

Useful resources

Physicians and medical students can fill their 'void' in objective clinical research by using the following sources:

Therapeutics Initiative • http://www.ti.ubc.ca
The Cochrane Collaboration • http://www.cochrane.org
The Medical Letter • http://www.medletter.com
Healthy Skepticism • http://www.healthyskepticism.org

The following sites will bring truth, justice and insight to all those wishing to improve the health of all people and uphold the integrity of the medical profession:

Student Physicians for Social Responsibility

• http://www.psr.org/spsr/

Physicians for Social Responsibility

• http://www.psr.org

No Free Lunch

http://www.nofreelunch.org

Canadian Centre for Policy Alternatives

• http://www.policyalternatives.ca

The Centre for Health Services and Policy Research

• http://www.chspr.ubc.ca

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