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DON'T TRUST THE HORSE

Examining the relationship between doctors and the medical industry

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INTRODUCTION

“Equo ne credite, Teucri. Quidquid id est, timeo Danaos et dona ferentes.”

“Do not trust the horse, Trojans! Whatever it is, I fear the Greeks, even bringing gifts.”

Words of Laocoön, the Aeneid

The story of the Trojan horse underlines the dangers of accepting gifts without considering the consequences. It is in this in mind that the relationship between the medical industry and healthcare professionals should be evaluated. Have we as a profession allowed a Trojan horse into the walls of our discipline?

THE PROBLEM

“There are few issues in medicine that bring clinicians into heated discussion as rapidly as the interaction between the pharmaceutical industry and the medical profession.” (Wazana 2000)

In recent times there has been renewed interest in the relationship between the healthcare provider and the medical industry. This may be in part due to the numerous prominent court cases involving pharmaceutical companies or the increasing recognition by both pharmaceutical companies and doctors need to correct unethical relationships (Blumenthal 2004; Blumenthal October 2004). While there is no doubt that pharmaceutical companies and other medical industries have significant roles to play in every healthcare system in the world, it is the degree to which this relationship affects the healthcare professional that demands further scrutiny.

A doctor's primary objective lies in improving or maintaining patient health, while acknowledging and attempting to maximise limited resource availability. Medicine differs from many other professions in that it is irrefutably bound to an ethical framework. Doctors and healthcare bodies should be committed to the health and well-being of those they serve and should act with integrity in compliance with the highest ethical principles and conduct (Panush 2004).

Although the medical industry has contributed many successful products to provide for the needs of the sick, it is an industry ultimately driven by profit, not altruism (Panush 2004). A natural conflict of interest then arises when one party tries to influence another that is bound by different ethical principles and ideals.

It is in this interaction, when the primary goals of the physician become blurred and aligned toward those of the medical industry (Tonelli 2007), that lies at the heart of the problem.

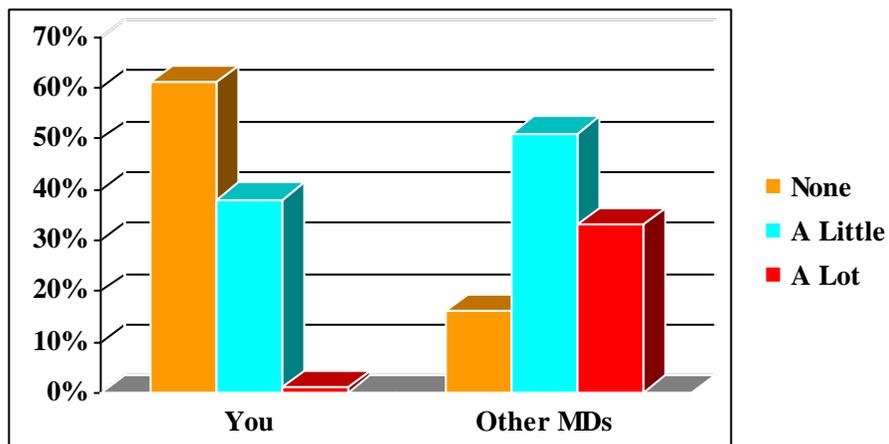
Doctors vehemently deny that the relationships between themselves and the medical industry have any negative effects (Chren 1999) and generally believe that they are not influenced by the educational content or gifts offered by the medical industry (M Steinman 2001). But it appears that doctors are no more immune to the influences of the aggressive marketing campaigns than any other person (A Wazana 2002).

The obvious question follows: What incentives are there for the medical industry to spend \$19 billion each year on marketing amongst doctors if there were no benefit in terms of increasing profit and shareholder value (Brennan 2006).

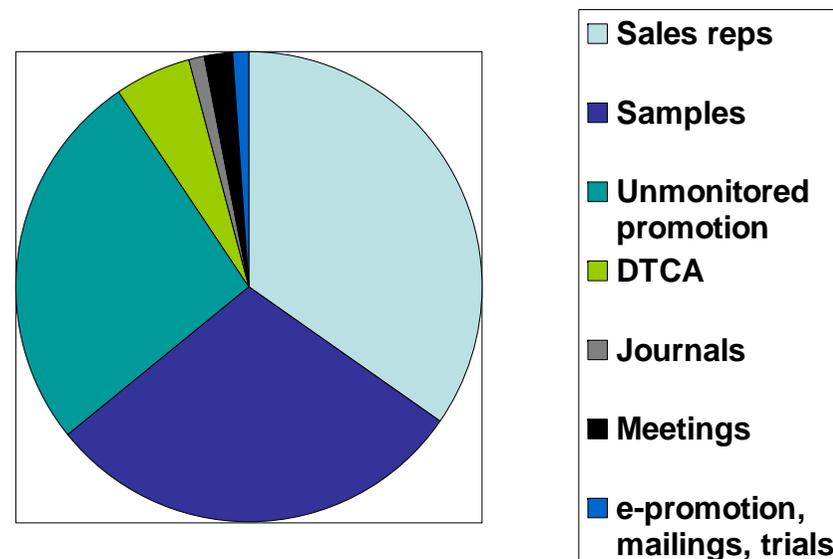
Doctors are also prone to thinking that the problem lies with other doctors and that they are not influenced by healthcare marketing ploys. This was evident in a study in which 61 percent of residents believed that they were not influenced by the marketing efforts of pharmaceutical companies, although they thought that a mere 16% of their colleagues were equally as discerning (Chren 1999).

Palmisano et al found that 85% of medical students believed it was unethical for a politician to accept a gift, but only 46% thought it wrong for themselves to accept a gift of similar value from a pharmaceutical company (P Palmisano 1980). However much healthcare professionals would like to think they are immune to marketing techniques, pharmaceutical companies disagree.

Perceived Influence of Pharmaceutical Reps (Steinman MA 2001)



\$57.5 billion in promotional spending in the U.S.A in 2004



Adapted from Gagno MA, Lexchin J. PLoS Medicine, 2008 (DTCA – direct-to-consumer advertising)

MARKETING

Marketing is a part of business and the subject of marketing ethics is one of great debate. Much of the marketing directed at the medical profession should be carefully examined and criticised, much as we do with peer reviewed articles.

The medical industry places enormous value in marketing and trying to change our practices, noted by the examples which follow.

- ✚ More than 30% of revenue is spent on marketing by pharmaceutical companies (Blumenthal 2004)
- ✚ Over 90% of the effort is aimed at physicians (Brennan 2006)
- ✚ Approximately 90,000 drug representatives (one per every five office-based physicians in the U.S.) (Blumenthal 2004)
- ✚ \$12–15 billion annually on gifts and payments to physicians (\$10–15,000 per physician per year) (Blumenthal 2004)
- ✚ US promotional spending in 2004 for pharmaceutical companies amounted to \$57.5 billion (Lexchin 2006)

Third World Marketing

Bala-Miller (Priya Bala-Miller 2007) discusses 3 areas in which the impact of marketing is felt in the Third World, namely, the rational use of medicine, the problems of access to medicines, and incorrectly used medication.

The rational use of medicine is compromised by the relative unavailability of independent research and literature with a disproportional reliance on pharmaceutical companies for drug information. This opens the door for the distribution of marketing information that may be inaccurate or biased and can lead to poor prescribing habits.

Access to medicines is often determined by cost. Obviously, this is linked to the debate regarding government licensing and the use of generics. The other issue is the cost of marketing, both direct-to-consumer and amongst doctors, and the effect this has on consumer pricing. It is also estimated that at least a third of the world's population cannot access the medication they require, and this reaches up to 50% in parts of Asia and Africa (Development 2006).

The wrong medication: The introduction of so called “me too” drugs that offer choices for treatment but without adding much medical value. Estimations by the DFID suggest that approximately 50% of patients in the developing world do not use the medicines correctly. This can of course have devastating consequences in terms of patient health and resistance to treatments (Development 2006).

There is little doubt that millions of lives could be saved annually if more research and development went into drugs that would benefit the healthcare systems of the world as opposed to those drugs that sell well, but the pharmaceutical industry is a profit driven business. It is, however, important that pharmaceutical companies do not allow their marketing to have negative impacts on drug prescribing and access (Priya Bala-Miller 2007).

Sales

While it's the doctors' job to treat patients and not to justify their actions, it's my job to constantly sway the doctors. It's a job I'm paid and trained to do. Doctors are neither trained nor paid to negotiate. Most of the time they don't even realize that's what they're doing...

—Shahram Ahari (former drug representative)
(Adriane Fugh-Berman 2007)

Pharmaceutical companies use sales representatives because of the personal approach they offer and because they are in a position to ascertain a doctor's feelings towards a product and where on the continuum of “unawareness – interest – usage” they lie (Priya Bala-Miller 2007).

They are often well trained in this task and pharmaceutical companies will use various techniques to influence healthcare professionals who have had little or no preparation for this interaction, for example;

- Gifts
- Food
- Psychological benefit (For example flattery, respite in a busy day)
- Friendship
- Information and articles
- Sponsorship and CME
- Financial gain
- Academic/ research gain

Books such as “Be brief. Be bright. Be gone. Career essentials for pharmaceutical representatives” make the following statements (Frost 2005);

“My company received 60,000 resumes for 500 open positions. You may have better luck...getting into Harvard, Yale, or Stanford than landing a sales slot at a major pharmaceutical company.”

“Consider this: countless pharmaceutical products are considered “me too” products. So part of your job may be to convince doctors that your drug is better, when....there is little or no difference at all. As I said, it is not an easy job.”

Fugh-Berman details in his 2007 study the different categories into which doctors may be placed for marketing purposes. He includes the different approaches adopted by the industry and how these techniques sell drugs.

Category of doctor	Technique
Friendly and outgoing	Based on a gesture of friendship
Aloof and sceptical	Journal articles to counter the doctor's perceptions, a scheduled appointment, play dumb and have the doctor explain the significance of an article
Mercenary	Closely associate the amount you are willing to spend on the doctor with the expectation of drug prescribing on the part of the doctor.
High-prescribers	Strong personal connections – friendship sells.
Prefers a competing drug	Understand why they're using another drug, give more attention than competitors, try to identify the drug to either capture another market niche, or simply expound it's superiority over competitors, try to wear the physician down by asking them to justify their prescribing practices.
Acquiescent docs	Gifts are used to enhance guilt and social pressure. Reps know that gifts create a subconscious obligation to reciprocate.
No-see/ No-time (hard-to-see docs)	Marketing the staff, provide staff with food and gifts during presentations; ask staff to discuss the usage of a drug with their patients.
Thought leaders	Groom for the speaking circuit, watch for tell-tale signs of their allegiance

Adapted from (Adriane Fugh-Berman 2007)

Attractive people have been used in sales for centuries and it is an important technique that we need to be aware of. In the United States certain pharmaceutical groups found a generous pool of potential sales representatives in the college cheerleaders who according to one source were employed for their enthusiasm and not their good looks (Saul 2005). An article in the New York Times (Saul 2005) describes how cheerleaders are "Known for their athleticism, postage-stamp skirts and persuasive enthusiasm, cheerleaders have many qualities the drug industry looks for in its sales force.... Drug companies have found that former cheerleaders are good at persuading doctors." Again this highlights the fact that doctors can be influenced.

The argument that drug representatives serve an educational purpose also needs to be addressed. If this were so, they would provide this service to all physicians, not just those who affect market share (Adriane Fugh-Berman 2007). The accuracy of their presentations is often questionable as the study by Ziedler showed a large percentage of statements made during presentations were false.(MG Ziegler 1995)

Finally, it should be known that pharmaceutical companies plan their marketing and target audience very well. For decades they have bought access to the American Medical Association Master File (Greene 2007), providing data on physicians prescribing practices, and have used this information to influence prescribing practices by identifying those doctors who require more, or less, attention.

1. Gifts

"Close and remunerative collaboration...naturally breeds goodwill...and the hope that the [beneficial relationship] will continue." (Panush 2004)

The giving of gifts is a well known promotional technique to influence health professionals' behaviour. It is well documented that even small gifts and samples promote feelings of obligation and brand loyalty (Hams 2007). Research in social science shows that the size of the gift or favour does not matter when creating feelings of obligation and reciprocity (D Katz 2003; J Dana 2003). "The obligation to directly reciprocate, whether or not the recipient is conscious of it, tends to influence behaviour"(D Katz 2003).

Some of the most important influences on behaviour include simple things like food, friendship, and flattery (J Dana 2003). And of course, as Dana mentions, these have formed an important part of friendship

since the beginning of time. It has also been shown that mortal human beings are inherently vulnerable to a powerful, unconscious "self-serving bias". To put it more simply, we deny that we are biased if the bias is serving our needs (J Dana 2003).

Further evidence shows: (Wazana 2000; DW McFadden 2006)

- that after interaction with a drug company, doctors are
 - more likely to prescribe a drug
 - more likely to prescribe a drug that is not clinically indicated
 - less likely to prescribe a generic
 - more likely to arrange for the drug to be placed on the hospital formulary
 - that doctors are more likely to write subsequent prescriptions after handing out free drug samples (LD Chew 2000)
- research that has a favourable outcome towards a drug is four times more likely to be published than an unfavourable result
- the above behaviour resulted in costly and non-rational prescribing

More interesting data found that the larger the number of gifts received by doctors, the more likely they were to believe that the gifts did not bias or influence them in any way (Wazana 2000).

Evidence from Gibbons et al (RV Gibbons 1998) indicates that patients are more likely than doctors to believe that the receipt of gifts influences prescribing practices and are viewed as inappropriate. Surely we have an obligation to safeguard our patients trust in a system which is coming under ever closer scrutiny?

2. Does gift giving really matter?

Bernard Shaw was spoken to in a flirtatious manner by an actress at a social event, and after a while inquired if she would spend the night with him for 50,000 pounds. She responded yes, but when he asked if she would do so for 10 pounds, became indignant, asking if he had mistaken her for a prostitute. "We have already established that, my dear," replied Shaw, "we are now merely haggling over price."

(Panush 2004)

Although to many it seems harmless and many doctors evaluate the system as fair and non-influential, there appear to be several conflicts of interest. These include:

- ✚ Prescribing behaviour and drug usage is affected by gifts and will affect public health and safety, drug usage and spending.
- ✚ The way in which the relationship between healthcare professionals and the industry is nurtured shows an indifference towards ethical practice.
- ✚ Gift giving often goes hand in hand with information distribution and opens an avenue for biased or misleading evidence. This is largely due to the relationship involving reciprocity and even lends itself to the situation of providing food for meetings.

In summary (Panush 2004), accepting gifts can result in the following:

- ✚ feelings of obligation, conscious or unconscious
- ✚ influencing doctors behaviour / prescribing patterns
- ✚ corrupting the concepts of (Gillon 1994)
 - distributive justice (unfairly allocating resources without patients' knowledge)
 - beneficence (corroding the physicians role as guardian of the patient's welfare)
 - non-maleficence (transferring costs to patients to fund gifts)
 - fidelity (obligating physicians to companies)
- ✚ attitudes of entitlement

Drug Promotion

The aim of promotion is to inform and to persuade. This takes many forms and is directed at both the direct consumer and physicians. The World Health Organization defines drug promotion as including: "all informational and persuasive activities by manufacturers and distributors, the effect of which is to induce the prescription, supply, purchase and/or use of medicinal drugs."

There are various methods used by drug companies to promote their product including advertisements, gifts to doctors, funding for events, and research (Europe 2002). Advertising, both direct-to-consumer and to the physician, is performed using many techniques.

These can be divided into:

- a) Techniques to win trust in a product
- b) Techniques to expand markets (also known as "disease mongering")

a) Techniques used to win trust in products include (Hams 2007):

- ✚ Trust in experts – "Dr X recommends this drug"
- ✚ Trust in peers – "Drug Z is the most frequently prescribed"
- ✚ Trust in people we like – "celebrities, sports stars, beautiful friendly people"
- ✚ Helping those who help us – gifts

b) Strategies to expand markets (Priya Bala-Miller 2007) (Mintzes 2006) include:

- ✚ Promotional campaigns to change consumer thoughts about common problems
 - Menopause becomes a hormone deficiency
 - Shyness becomes social anxiety disorder
 - Acid indigestion becomes gastroesophageal reflux disease
- ✚ Widening the indications
- ✚ Appeal to fear/anxiety – increasing the perceived likelihood of harm without the drug
- ✚ Promoting medication for milder symptoms
- ✚ Appealing to the idea of scientific breakthrough – unique, new, first of it's kind

The concept that advertising sells is demonstrated successfully in the aggressively marketed United States, where 5% of the worlds population accounts for 50% of the world's drug consumption.

Advertising in journals has also resulted in ethical and financial problems as demonstrated in 1992. The Annals of Internal Medicine published an article that critically evaluated the scientific accuracy of advertisements placed in 10 leading journals. They concluded that 34% of the adverts should have been reviewed before publication and 28% should never have been published. As a result the Annals lost \$1-1.5 million in advertising revenue. The editor at the time said, "The episode revealed the true colours of the pharmaceutical industry, which was willing to flex its considerable muscles when it felt its interests were threatened" (Lexchin 2006).

Advertisements make journals economically viable but provide for the potential conscious and unconscious influence that may affect editors' decisions to publish.

Revenue from advertisements in six major US medical associations and journals

Journal	Organisation	Revenue		% of membership fees and assessments
		Annual (\$m)	% of total	
<i>Journal of American College of Cardiology</i>	American College of Cardiology	4.7	13.8	93.0
<i>Annals of Internal Medicine</i>	American College of Physicians	6.0	12.9	133.9
JAMA	American Medical Association	18.6	10.4	26.2
<i>American Journal of Respiratory and Critical Care Medicine</i>	American Thoracic Society	0.7	2.1	17.1
<i>Clinical Infectious Diseases</i>	Infectious Disease Society of America	0.7	31.3	125.4
<i>New England Journal of Medicine</i>	Massachusetts Medical Society	14.3	21.3	792.7

(Lexchin 2006)

Direct-to-consumer drug promotion also has clear benefits in terms of sales. It can be argued that it also increases the rate of treatment, but research shows that it increases both appropriate and inappropriate treatment (Foundation 2002). This is clearly an area which requires closer regulation.

Direct-to-Consumer Expenditures (Julie M. Donohue 2007)



Advertisements also tend to favour new, expensive treatments, and sometimes for new conditions that may still be controversial. There is a need for renewed scepticism when new drugs enter the market.

Control of the various interventions used by companies is only successful with government regulation, education of students and doctors, exposure of abusive promotion, and "free and abundant availability of non-commercial therapeutic information". (Europe 2002)

In May 2007 at the 60th World Health Assembly, an agreement was reached pertaining to a resolution on the rational use of medicines. The resolution aims to "enact new, or enforce existing, legislation to ban inaccurate, misleading or unethical promotion of medicines, to monitor drug promotion, and to develop and implement programmes that will provide independent, non-promotional information on medicines." (Assembly 2007)

In summary:

- Companies are motivated by profit, and not altruism (Panush 2004).
- The primary mission is to generate profit and increase shareholder value.
- Effective marketing helps to achieve this mission.
- Vast amounts are spent in the marketing of prescription drugs.
- The aim of this sophisticated marketing is to influence health professionals' decision making.
- Marketing of doctors starts at medical school where little or no teaching on this subject is offered to students (Blumenthal 2004).

CONFLICTS OF INTEREST

A conflict of interest arises when personal interests are in opposition to professional duties. (Tonelli 2007) (Steinbrook 2009) We need to differentiate daily conflicts of interest, for example our duty to a patient may conflict with the wishes of their family (Tonelli 2007), from those that are ethically disturbing. Steinbrook classifies these areas of concern into primary and secondary (Steinbrook 2009). The primary interests of concern include "promoting and protecting the integrity of research, the welfare of patients, and the quality of medical education." Secondary interests "may include not only financial gain but also the desire for professional advancement, recognition for personal achievement, and favours to friends and family or to students and colleagues" (Steinbrook 2009). The attention of the public, media and doctors is on financial conflicts of interest. These are certainly more quantifiable and objective, but are not necessarily more corrupting.

Continuing Medical Education

The pharmaceutical industry invests massive sums in CME. In 2003, pharmaceutical companies were providing about \$900 million which amounted to 90% of the amount spent annually on CME. In the USA the Accreditation Council for CME (ACCME) has certified numerous private, for-profit companies, known as medical education and communication companies, to present accredited CME programs. Almost all of these companies are underwritten by pharmaceutical companies (Steinman MA 2007) .

The concept of CME is here to stay and is vital for the distribution of new information and techniques in health care. But we should be careful not to allow the interference of profit based industry to tarnish the perception of scientific objectivity and training (Steinman MA 2007). Appropriate regulation is being implemented to protect the physician in these CME activities, but we need to be mindful of the influences.

Currently, the medical industry and doctors CME are intimately entwined, but the relationship needs to be questioned. How much involvement should the medical industry have in CME and can CME continue without industry support? Consideration needs to be given to the value added by the financial support to CME, but an opposing view can equally predict harm from this involvement:

- ✚ **Good** - New therapies and innovations offering patient benefit are introduced to doctors
 - Doctors are provided the opportunity to hear up to date information
- ✚ **Bad** - Allowing a profit driven industry to influence and decide on content, speakers, and what constitutes the most appropriate for doctors to learn about

This will only be a problem when the industry tries to persuade the healthcare professional towards a practice or product that is more likely to benefit the industry than the patient (Steinman MA 2007).

In summary:

- ✚ Conflicts of interest can arise out of the financial incentive for CME organizers to create educational programs that present companies' products favourably (Steinman MA 2007).
- ✚ Educational grants, CME fees and speaker's fees are gifts that engender feelings of reciprocity mentioned earlier, and result in altered course content. Expectations of reciprocity, personal relationships, and fear of disrupting established relationships with companies can discourage speakers from presenting negatively about a company's product (Steinman MA 2007).
- ✚ Doctors' unwillingness to pay for their own CME may ultimately result in a more costly loss of public trust and faith in the profession (Brennan 2006).

Medical Research

The medical industry is closely linked to medical research, funding clinical trials that are likely to favour its products, helping with design, analysis and eventually publication. However, analysis of data by pharmaceutical companies, ghost writers, and suppression of unfavourable evidence has all come to light in a variety of court cases during the last decade.

Some examples are listed below:

- ✚ Authors supporting the safety of calcium-channel blockers were more likely to receive industry funding than those who did not (HT Stelfox 1998).
- ✚ 3 major studies without industry funding found a higher risk of DVT for 3rd generation contraceptives. 3 sponsored studies did not (J P Vandembroucke 2000).
- ✚ Only 2.1% of subjects in NSAID trials were >65yrs, although NSAIDs are more likely to be used by this group with more side-effects (PA Rochon 1998).
- ✚ In 1996 Olivieri and colleagues found that deferiprone, used in the treatment of thalassaemia major, could worsen hepatic fibrosis. Apotex threatened legal action if the authors published the data (RA Phillips 1998).
- ✚ A study showed that 19% of original articles surveyed had named authors who would not meet the International Committee of Medical Journal Editors criteria for authorship. Of these 11% had ghostwriters (Rennie 1998).

There is an undoubted pressure on the physician to publish and this will contribute to shortcuts and industry involvement as the quest for publications drives further research. Dr Peter Wilmshurst summarises it best when describing the need for “a change in the culture in medicine in which research success is viewed as the passport to success in ones career”. (Wilmshurst 2003)

a. Drug Research and Scandals

The subject of drug research and scandals is a considerable one and I will only touch on a few areas. The revenue allocated towards research and development of new drugs is only a relatively small percentage of the total cost spent on drugs (Reinhardt 2003). This is in comparison to the estimated \$57.5 billion spent on marketing in 2004, nearly twice that which was spent on research and development.

The French journal *La Revue Prescrire* reviewed the new products approved in France between 1981 and 2004 and found that 68% of the 3096 drugs brought “nothing new” to the treatments already on the market (*Prescrire* April 2005). It also remains that some of the more devastating, widespread diseases are neglected, particularly those in Africa. Only 1% of drugs released onto the market between 1974 and 2004 deal with these conditions (R Gillies 2006).

Without going into too much detail, it is evident from Studdert et al (Studdert DM 2004) that certain pharmaceutical companies have participated in ethically and possibly legally dubious work to change prescribing practises. These include episodes of kickbacks, bribes, and gifts as payback.

Some of these controversies have involved:

- ✚ **Activated protein C** and the “Surviving Sepsis Campaign” (Eichacker PQ 2006)
- ✚ **Cotrimoxazole** and its seemingly nonclinical basis for its combination with trimethoprim, despite resulting in numerous anaphylactic reactions (Deer 1994)
- ✚ **Gabapentin** and the involvement of marketing firms, ghost-writers, and claimed benefits for unapproved use. Pfizer (acquired Parke-Davis, paid \$430 million in fines (*NY Times*, May 15 2002)
- ✚ **Vioxx** and a seeding trial (designed by Merck’s marketing division), used gifts, grants, and donations to win over opinion leaders and

may have known about CVS risks earlier than 2004 (*Hill 2008*) (Topol October 2004) (Lee March 2008)

- ✚ **Lupron** whereby free samples of this expensive prostate cancer drug were administered to patients and subsequently billed to Medicare (DW McFadden 2006)

b. Guidelines

Guidelines should also be carefully reviewed and considered for bias. This is corroborated by evidence from Choudhry et al (Choudhry NK 2002) who found that 59% of the authors involved with clinical guidelines, many of which are supported by professional associations, have had financial links with pharmaceutical companies whose drugs may be affected by the guidelines.

An example would be the class 1 (definitely recommended) intervention by the American Heart Association (AHA) for the use of alteplase as an intervention for stroke. Many of the experts involved had undisclosed ties with Genentech, the manufacturers of alteplase. This company contributed \$11 million to the AHA over the previous 10 years before the recommendation was made. The AHA was forced to eventually retract its statement that alteplase saves lives for stroke, but only after rigorous public analysis.

These problems may not always be that easy to discern. Detsky et al (Detsky 2002) surveyed 192 authors of 44 clinical practice guidelines and found that 87% of them had some interaction with the pharmaceutical industry. However, in the published versions of the guidelines, only 2 cases were found where specific disclosures about personal financial interactions were made.

This highlights the need for us to be ever more vigilant about our scrutiny of medical literature and published guidelines.

c. Seeding Trials

Seeding trials are clinical studies conducted by pharmaceutical companies that are designed to seem as if they answer a scientific question but primarily fulfil marketing objectives. (Hill 2008)

There have been numerous examples in the past, famously the Vioxx scandal as mentioned earlier. New articles need to be closely examined

for evidence of seeding trials and education of medical student and trainees with regards to critically appraisal should remain a priority.

d. Industry Supported Drug Trials

A recent article comparing Cochrane reviews with those of industry supported meta-analyses of the same drugs found that of the industry supported reviews all recommended the drug without reservation. None of the Cochrane reviews came to the same conclusion and this was similar to reviews with not for profit support or no support (Jørgensen 2006).

Gross et al (Gross 2003) looked at the extent and impact of financial conflicts of interest in biomedical research. Their results showed that about 25% of investigators have industry affiliations and there was a significant association between industry sponsorship and conclusions that supported the industry. Data sharing and restriction of publications was also influenced with industry sponsorship. They concluded that the financial ties with the industry can influence biomedical research in important ways.

In another study by Yank et al (V Yank 2007) of 124 meta-analyses (40% of which had financial ties to a pharmaceutical company), financial ties to a drug company were not associated with favourable results but were associated with favourable conclusions.

It is clear that industry supported medical research should be viewed with suspicion and journals should probably be more vigilant and cautious when it comes to publishing. A demerit system should be considered when a journal is found to publish data or articles that have been influenced by the medical industry.

MEDICAL INDUSTRY REGULATION

Member governments are urged, "to enact new, or enforce existing, legislation to ban inaccurate, misleading or unethical promotion of medicines, to monitor drug promotion, and to develop and implement programmes that will provide independent, non-promotional information on medicines."

Resolution Rational Use of Medicines (WHA 60.16)
Adopted by the 60th World Health Assembly May 2007

It is apparent that governmental regulation of pharmaceutical companies is under scrutiny; however it is likely that the systems in developing countries will lag behind those of the first world. Mintzes (Mintzes 2006) noted that in 2004 the World Health Organisation only identified a well-developed system of drug regulation in less than 17% of countries and about 30% had no regulatory legislation. This lends itself to the exploitation of unethical and irresponsible promotion of drugs to both physicians and consumers.

Regulation of drug promotion is an obviously difficult task with many obstacles.

These include:

- The massive economic power of pharmaceutical companies
- Detection of unethical or misleading practices requires knowledge and skills in the areas of pharmacology, marketing, psychology, economic, semiotics (the study of the meanings conveyed by images) and linguistics (Priya Bala-Miller 2007)
- Detection of inappropriate gift giving and drug promotion requires a level of policing that not many countries can afford

Certainly concern over the relationship between the medical industry and doctors has resulted in improved policy making over the last 5 years. In the United States, this has included reporting on how much is spent on marketing products to physicians, monitoring gifts of more than \$25, (Blumenthal 2004) and the Physician Payments Sunshine Act of 2007 (disclosure of physician payments)(Campbell 2007). Transparency should be our goal with a renewed trust in our profession. The data collected under the new state mandates in the US may not always be that useful, but the move towards transparency in gaining momentum (Campbell 2007).

However, should the onus fall solely on the government and industry? If the medical industry is legislated to disclose physician payments, then possibly physicians should subscribe to disclosing any amount of revenue or product from companies on a national website so as to increase transparency. The Boston University School of Medicine and Boston Medical Centre announced a new conflict-of-interest policy on the same day that the new Sunshine Act was introduced. This policy served to regulate the influence of the medical industry on its students, doctors, research, and hospital drug-selection committees (Campbell 2007).

A simple test for the individual researcher is the "Wall Street Journal Test" – if they fail to disclose a financial relationship the investigator must decide if it would be embarrassing if it was discovered at a later date and scrutinised by the public (Moy 2008).

DISCUSSION

"It is time for medical schools to end a number of long-accepted relationships and practices that create conflicts of interest, threaten the integrity of their missions and their reputations, and put public trust in jeopardy."

- Institute of Medicine. Conflict of Interest in Medical Research, Education, and Practice, 2009

The relationship between the medical industry and healthcare professionals is complex and is open to manipulation, influencing the healthcare professional to align their actions with the goals of the profit driven pharmaceutical and medical equipment industry. The industry targets health professions with gifts, flattery and friendship, because doctors hold buying power. Doctors are vulnerable and, more conveniently believe that they are invulnerable.

The concept of having conflicts of interest is universal in the practice of medicine, but our response demands more than an attitude of denial or admission of defeat. The well-being and care for our patients and the very integrity, ethical and moral principles on which we base our practice are at stake.

Some critics feel that the only way in which to approach this problem is to cut all ties with the medical industry and not to accept anything financial from drug companies. This is in the light of only 13% of the American public believing that pharmaceutical companies are "generally honest and

trustworthy," (Harris Poll survey 2004), putting them on a par with tobacco and oil companies (Lenzer 2004). This view is endorsed by the American Medical Student Association. (WA Rogers 2004) However, a more considered approach is adopted by others (Stossel 2008), believing that doctors' rewards should not be regulated, legislation is in place to protect physicians, and that reasonable doctors should be able to judge for themselves.

The evidence presented, however, indicates that this is not the case. We are influenced by the medical industry's marketing, we consider our colleagues to be more easily influenced, and there is worldwide disparity in terms of legislation, particularly in the Third World (Priya Bala-Miller 2007). Gifts are used to persuade and manipulate. Evidence has also shown that the size of the gift does not matter when it comes to influence and feelings of reciprocity. As mentioned earlier, the acceptance of gifts involves the corruption of the concepts of distributive justice, beneficence, non-maleficence, and fidelity (Gillon 1994).

In South Africa, the main documents controlling legislation include the HPCSA Ethical Guidelines and Undesirable Business Practices (Africa September 2005), the Health Professions Act of 1974 (Ethical rules of conduct for practitioners)(Government 1974), National Health Act and Medicines Control Act(Health 2003), and the South African code of Practice for the Marketing of Medicines(Committee 31 March 2009), although they appear fairly scant on details. For example, there is a clause for the giving of cultural gifts up to a value that is "in line with the value of general gifts" (Committee 31 March 2009).

New legislation and tighter controls will probably make it more difficult for medical industry, but ultimately healthcare professionals will still need to assess their stance on matters. Equally, one-on-one relationships are going to become more important as marketing tools as gift-giving becomes more restricted.

Recommendations (Priya Bala-Miller 2007)

Disclosure alone is certainly not the answer as most patients are unable to choose their health providers or health care system and most CME speakers and programmes have had some relationship with the industry (Tonelli 2007). Disclosure without avoidance is not effective. If we fail to move beyond disclosure then we are neglecting our responsibilities to our patients and our colleagues.

Both the individual and the organisation (universities, journal committees, governments, and pharmaceutical companies) need to evaluate their position in the relationship in question.

Academic departments should carefully assess their relationships with the medical industry. The need for a formal policy regulating this relationship should be considered. Education on good principles in prescribing and understanding the ethical dilemmas surrounding this subject is alarmingly absent lacking both amongst undergraduate and postgraduate training. This is an area that could be relatively easily rectified and result in a more informed and prepared generation of doctors.

(See Appendix A for a full list of recommendations)

Recommendations to Physicians (S Chimonas 2007)	Recommendations to Academic Centers (Priya Bala-Miller 2007)
<ul style="list-style-type: none"> ✚ Annual workshops for new residents and students discussing these issues ✚ Peer-reviewed research should be available from drug representatives (David W. McFadden 2007) ✚ Identify and use unbiased and independent sources of prescribing information ✚ Opt-out to limit use of AMA master profile ✚ Attend CME programs with less or no industry sponsorship (Michael A. Steinman October 2007) ✚ Distribute peer-reviewed articles on drugs etc prior to company visits ✚ Consider company visits but only in a formal setting without time for relationship building 	<ul style="list-style-type: none"> ✚ Contributions from the medical industry to a conflict free central facility (for CME, speakers, travel etc) ✚ Eliminate speakers' bureaus and ghostwriting ✚ Eliminate all gifts, meals directly to physician from industry ✚ Transparency for consulting, speaking honoraria, and research contracts - published on department website for public inspection ✚ Only conflict fee members to advise on formulary and other purchasing decisions (Rubin 1994) ✚ Contracts between industry and researchers allowing freedom to publish trials ✚ Public funding of trials that matter ✚ Reviews and guidelines: should they exclude sponsored authors or at least set a maximum level of industry support?

CONCLUSION

It should be the moral imperative of doctors to consider their patients welfare first. Actions which discourage this, whether conscious or unconscious, should be brought to light, examined, and changed. It does not matter whether or not doctors believe in the power of marketing and advertising. The medical industry knows that it works and invests billions of dollars annually. Denial will not prevent the problems between doctors and the medical industry from continuing. The first steps to rectifying the problems with the relationship between doctors and the medical industry is recognition and acknowledgement (Tonelli 2007).

The practice of doctors relinquishing their responsibility to educate themselves (Panush 2004), allowing free access to medical students and academic departments, and the strong influence on CME and research, needs urgent review and correction. At the very least, every doctor needs to critically evaluate their stance and decide if their actions are protecting their patients and students, benefiting society, and building trust for a profession which has lost much ground in the public's eyes over the last few decades. Trust and credibility need to be earned, but once lost, are difficult to restore (Lee March 2008).

Pharmaceutical companies will continue to aggressively market their products. This can be expected, provided it is within legal boundaries (Blumenthal October 2004). However, we can choose to do business on our terms and make a conscious effort to avoid the potential influence, minimising the opportunity for persuasion. Both the medical industry and health care providers will need to carefully appraise their responsibilities to their patients and shareholders as this relationship is transformed (David W. McFadden 2007).

In the city of Troy, the priest Laocoön and the King Priam's daughter, Cassandra, predicted the ploy used by the Greeks. The priest was eliminated and Cassandra was ignored. We need to carefully evaluate our involvement with the medical industry and accept that we are allowing Trojan Horses into our midst, and we must remember that the Trojans never regained their land or power again.

Into whatever houses I enter, I will go into them for the benefit of the sick, and will abstain from every voluntary act of mischief and corruption;
 Hipocrates (about 400 BC)

RECOMMENDED READING

1. EG Campbell. Doctors and Drug Companies — Scrutinizing Influential Relationships. *New England Journal of Medicine* vol 357 (18); 1796-1797.
2. DW McFadden et al. The Devil Is in the Details: The Pharmaceutical Industry's Use of Gifts to Physicians as Marketing Strategy. *Journal of Surgical Research* 2006 vol 140; 1-5.
3. J Lexchin. Commercial influence and the content of medical journals. *BMJ* 2006 vol 332; 1444-7.
4. A Wazana. Physicians and the Pharmaceutical Industry: Is a Gift Ever Just a Gift? *JAMA* 2000 vol 283 (3); 373-380.

APPENDIX A

Recommendations to Physicians (S Chimonas 2007)	Recommendations to Academic Centers (Priya Bala-Miller 2007)
<ul style="list-style-type: none"> ✚ Annual workshops for new residents and students discussing these issues ✚ Peer-reviewed research should be available from drug representatives (DW McFadden 2006) ✚ Identify and use unbiased and independent sources of prescribing information ✚ Opt-out to limit use of AMA master profile ✚ Attend CME programs with less or no industry sponsorship (Michael A. Steinman October 2007) ✚ Distribute peer-reviewed articles on drugs etc prior to company visits ✚ Consider company visits but only in a formal setting without time for relationship building 	<ul style="list-style-type: none"> ✚ Contributions from the medical industry to a conflict free central facility (for CME, speakers, travel etc) ✚ Eliminate speakers' bureaus and ghost-writing ✚ Eliminate all gifts, meals directly to physician from industry ✚ Transparency for consulting, speaking honoraria, and research contracts - published on department website for public inspection ✚ Only conflict fee members to advise on formulary and other purchasing decisions (Rubin 1994) ✚ Contracts between industry and researchers allowing freedom to publish trials ✚ Public funding of trials that matter ✚ Reviews and guidelines: should they exclude sponsored authors or at least set a maximum level of industry support?
Recommendations to government (Priya Bala-Miller 2007)	Recommendations to the medical industry (Priya Bala-Miller 2007)
<ul style="list-style-type: none"> ✚ Clinical trials registries (Hams 2007) ✚ Implement, improve and monitor legislation in line with the WHO Resolution on the Rational Use of Medicines and the WHO Ethical Criteria for Medicinal Drug Promotion ✚ Support the provision of independent information on drugs for consumers and health professionals ✚ Implement and enforce a ban on gifts to doctors ✚ Enforce strict sanctions that will deter poor corporate practice in drug promotion. ✚ Take measures to improve the transparency of drug companies' marketing activities and seriously address the conflict of interest encountered in drug ✚ prohibit the use of sale prescriber data from the marketing campaigns of pharmaceutical companies 	<ul style="list-style-type: none"> ✚ Stop the practice of gifts to doctors ✚ Implement rigorous policies on vetting of drug promotion materials and adherence to existing codes of conduct ✚ Provide transparent and verifiable information on the precise nature of relationships and associated funding for all stakeholder groups, including health professionals, pharmacists, students, journalists, clinical research organisations and patient groups. ✚ Ensure codes of conduct on drug promotion extend to interactions with health professionals AND consumers. ✚ Invest in innovative partnerships with government and civil society organisations so that corporate funding of disease awareness campaigns and CME may be channelled via blind trusts in line with specific health priorities of consumers at a community or national level.

Recommendations to journals (Lexchin 2006)	Recommendations or CME
<ul style="list-style-type: none"> <li data-bbox="107 188 555 284">✚ Detailed information about sources of income, including amounts from the sale of reprints, supplements, and advertising should be published <li data-bbox="107 290 555 363">✚ Recommendations from the Committee on Publication Ethics (COPE) should be followed <li data-bbox="107 370 555 443">✚ Editors and editorial teams should disclose their own relevant conflicts of interest <li data-bbox="107 450 555 539">✚ Journals should consider not allowing editors to have any direct financial ties any healthcare business that advertises in the journal that they edit; <li data-bbox="107 545 555 651">✚ The International Committee of Medical Journal Editors (ICMJE) or the World Association of Medical Editors should record financial interactions of authors and publish these statements 	<ul style="list-style-type: none"> <li data-bbox="568 165 1016 188">✚ Minimise industry involvement in CME <li data-bbox="568 194 1016 268">✚ Decrease travel cost by using web-based technology to broadcast conferences online <li data-bbox="568 274 1016 316">✚ Fund CME events from an industry supported central pool (Brennan 2006) <li data-bbox="568 322 1016 363">✚ Refusing to host events sponsored by a single company (Marlow 2004) <li data-bbox="568 370 1016 443">✚ Use prospective risk assessment tools to identify activities at greater risk for bias (Marlow 2004) <li data-bbox="568 450 1016 491">✚ Post-attendance questionnaires to assess bias (Marlow 2004) <li data-bbox="568 497 1016 587">✚ Critically evaluate the course faculty and speakers with regards to their disclosures, topics presented and their involvement with industry