

# “The Need to Develop Responsible Marketing Practice in the Pharmaceutical Sector”

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# The Need to Develop Responsible Marketing Practice in the Pharmaceutical Sector<sup>1</sup>

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## Abstract

This paper identifies and discusses current marketing practice in the pharmaceutical sector, as it relates to therapeutic pharmaceuticals. It examines the potential risks associated with certain marketing practices, such as the impact of misleading advertising and the possibility of disease mongering. The methods currently used to regulate industry promotion practice are critiqued and suggestions are made for improvements, including a move from industry self-regulation to an independently monitored code of practice for pharmaceutical marketing.

**Key words:** Pharmaceutical marketing, advertising.

## The context

In May 2003 the *British Medical Journal* devoted a special edition to the relationship between doctors and pharmaceutical companies entitled “*Time to untangle doctors from drug companies*” (Moynihan, 2003). This examined the relationship between the medical profession and the pharmaceutical industry (Big Pharma). The medical profession in Europe, in conjunction with many social movements, has begun to consider seriously the appropriateness of current relationships between Big Pharma and the health sector. This is occurring in the context of legal actions around corrupt sales practices in Europe such as those against GlaxoSmithKline (GSK) in Germany (Gopal, 2002) and Italy (Turone, 2003), and the major action against TAP Pharmaceutical Products, Inc in the United States which resulted in a \$875 million dollar settlement in 2001 (Riccardi, 2002).

This debate is already very strong in the United States where it has further extended to encompass the relationships between Big Pharma and consumers. This is in part because of US practice of allowing direct-to-consumer advertising (DTCA) of prescription drugs. Industry organs such as PhRMA the umbrella organization of the American pharmaceutical industry argue that such advertising (properly regulated) allows consumers to inform and educate themselves about therapeutic options and achieve a more equal relationship with their physicians. On the other hand, action groups such as the U.S. Public Citizen’s Health Research Group oppose this practice as they contend that there is no evidence that such advertising improves health care ([www.worstpills.org](http://www.worstpills.org)).

Big Pharma is in many ways the ultimate marketing example. They engage in multi-million dollar marketing campaigns, use all methods of promotion from mass media advertising, to below the line spend on measures such as the engagement of key opinion leaders. Many billions of dollars have been spent on developing and protecting not alone their branded products but also their component drugs internationally.

## How are drugs promoted?

The average cost to bring to market a so-called blockbuster drug has been estimated at \$895 million (EFPIA, 2002), though there are those who question the accuracy and transparency of such figures (Light and Lexchin, 2003). Even if we accept that the actual cost of development may not always be as high as the EFPIA estimate, all would accept that there are still significant research and development costs that must be recouped in sales.

Depending on the category of drug the nature of the marketing mission is different. There are essentially two categories of drugs: self-medication or over the counter (OTC) drugs, and prescription drugs – sometimes referred to as ethical drugs (de Mortanges and Rietbrock, 1997). OTC

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drugs are promoted directly to consumers as well as physicians and other healthcare professionals and range from analgesics such as paracetamol to anti-histamines. What is categorized as OTC varies from country to country and is dependent on the local legislative framework, usually a national medicines authority. So for example in the United States some anti-histamines are prescription-only, while in some European countries some antibiotics may be bought over the counter.

There are four main buying parties for prescription drugs (Corstjens, 1991):

- Prescriber – prescribing rights vary internationally and this category may include doctors, dentists, pharmacists, nurses and optometrists
- Influencer – hospitals, nurses, professors, reimbursement agencies
- Consumer – patient
- Financier – partly patient, partly government or third party (varies by country), managed health care organization (hospitals, Health Maintenance Organisations etc.)

Currently the majority of Big Pharma's marketing budget is targeted at doctors and others with prescribing powers, who are effectively the gatekeepers to drug sales. In 2002 the Canadian Medical Association Journal estimated Big Pharma spends some \$19 billion annually in promoting drugs to doctors in the United States alone. The methods used will be discussed later in this paper.

In the European Union only OTC drugs are promoted directly to consumers. Examples include analgesic preparations and some ailment-specific drugs such as the Schering Plough blockbuster Claritin – a hay fever remedy. In 1998 Schering Plough spent \$186 million promoting Claritin, and as a result saw a half a billion dollar increase in sales year on year to achieve annual sales of \$1.9 billion, (Maguire, 1999).

In the United States all drugs may be promoted to consumers, but in practice direct-to-consumer advertising focuses on OTC and common-ailment targeted prescription drugs. There are other more limited application drugs for less common diseases that are only promoted to health care professionals, and hospital and organizational formulary committees (such as HMO formulary committees). The drug marketing process can be described by the model below in Figure 1, which shows the information flow from drug companies, both to consumers and doctors. It also shows the power that consumers, informed by DTCA and the Internet, have in "pulling" prescription drugs from doctors.

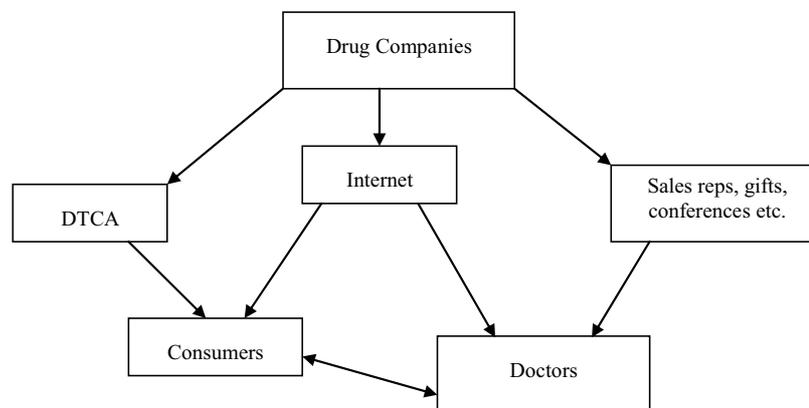


Fig.1. Pharmaceutical marketing communication process

Figure 1 describes the pharmaceutical marketing communication information flows. Drug companies communicate in three main ways – direct to consumers through broadcast and print advertising, on the internet through advertisements and company websites, and through company funded direct selling/sponsorship (either by drug sales reps, funded conferences/meetings, paid experts). These various methods will be discussed in more detail below, but it is worth noting here that in the case of the Internet the information is targeted at both consumers and doctors, and that

the availability of information from DTCA and the Internet has created an increased information flow between doctors and consumers (Eagle and Kitchen, 2002).

### **Creating the Pull – Directly and Indirectly**

Historically promotion for prescription drugs occurred only from manufacturer to prescriber so that physicians and others with prescribing powers were the gatekeepers to eventual drug sales. The promotion strategies therefore were all essentially “push” focused. However the decision in 1997 by the US Food and Drugs Administration (FDA) to relax restrictions on broadcast DTCA of these drugs has resulted in increased “pull” from consumers. In both the United States and New Zealand DTCA of prescription drugs occurs with considerable effect, as will be discussed below. A further source of ‘indirect’ pull has been the impact of the Internet on pharmaceutical promotion, which will also be discussed below.

#### **Direct to consumer promotion – creating direct pull**

In August 1997 the US FDA made significant changes in the regulations for broadcast DTCA of prescription drugs. Prior to 1997 DTCA had to include the entire brief prescribing information which meant that about 30 seconds out of a 60 second advertisement would consist of fine print scrolling across the screen. In 1997 the FDA dropped this requirement and said that DTCA had to mention the major side-effects, and also provide other ways that consumers could get more information about the drug (e.g. give a web site, a 1-800 number or refer to a print ad for the same product which contained the same information) and tell consumers to consult their doctors/pharmacists. In the four-year period from 1996 to 2000 promotional spend direct to consumer within the United States tripled (from \$791 million dollars to \$2.5 billion dollars<sup>1</sup>). New Zealand is the only other developed country that allows DTCA of prescription drugs. Burton (2003) details a report by academics from all of New Zealand’s medical schools that recommended that the practice be discontinued. This report, based on a survey of all general practitioner doctors in New Zealand, found out that 75% of respondents believed DTCA to be negative with patients frequently requesting drugs that were inappropriate to them. On the other hand in New Zealand drug advertising is not monitored by a state agency (whereas it is in the United States). The pharmaceutical and advertising industries are self-regulating. This leads to a less than ideal situation where only a small percentage of the televised pharmaceutical advertisements are compliant with the New Zealand Medicines Act regulations, which ostensibly control information on contra-indications, and safety and quality of medicines – known as pharmacovigilance.

#### **Effects of DTCA on consumers**

According to Flynn (1999) DTCA makes consumers better informed and more sophisticated. In his view consumers are enabled, through DTCA, to better understand the market for drugs and the therapeutic options available to them. This view is shared by Calfee (2002), who argues that consumers can engage in more equitable relationships with health care providers and become partners in their own health care as a result of DTCA. Mintzes *et al.* (2002) found that consumers pulled prescription drugs through the system, going to physicians with requests for medications that they had learnt of through advertisements. Their research showed that patients normally got positive responses to requests for prescriptions. Their research also showed that physicians were influenced in their choice of drugs and might otherwise have prescribed different drugs.

In 1999, Maguire suggested that American physicians were being asked to ‘rubber stamp’ self-diagnoses and self-prescriptions by patients. Citing a study by *Prevention* magazine of the previous year she suggested that 15.1 million U.S. consumers asked their physician for a medication they saw advertised, and that physicians honoured those requests 80% of the time, which translates into 12.1 million prescriptions generated by advertising. Further evidence of the effectiveness of DTCA is the fact that visits to doctors for conditions covered in advertising campaigns rose 263% in the first

<sup>1</sup> New England Medical Journal 14/2/02.

nine months of 1998, in comparison with a general 2% rise in visits to doctors. Lexchin and Mintzes (2002) examining the relationship between DTCA and prescribing practices find that DTCA does affect doctors' prescribing patterns, which they suggest is not always a positive development. They give as an example General Motors' 1999 internal study of the prescription of the gastrointestinal drug Prilosec (the second most heavily DTC promoted drug in 1999) to its employees. GM found that 92% of those who received a prescription for Prilosec had not received a previous prescription or even consulted a doctor previously for gastrointestinal problems. Most received Prilosec as a first line drug without first trying other cheaper and less intensive treatments. Lexchin and Mintzes argue that this is evidence that DTCA has impacted prescribing patterns, effectively creating consumer pull for in some cases inappropriate therapies.

#### **Creating pull indirectly**

Besides the impact of DTCA, increasingly consumer pull for drugs is being created indirectly by Internet promotion, and, perhaps more questionably, by partnerships with patient support groups.

### **The Impact of the Internet**

Consumers are able to purchase all kinds of prescription drugs online often without need for a prior prescription. Research conducted by Bloom (1999) and the American Medical Association (reported in Kohn and Henderson 2004) showed that most Internet pharmacies provide poor quality information, fail to have adequate safeguards to ensure medicines are dispensed correctly, and also charge more for both products and services. Smith (2003), referring to an Australian study, found out that online pharmacies often lacked important information about contraindications for medications available on their sites. However even if one sets aside the impact of Internet pharmacies, on the basis that the additional costs may put them outside the reach of consumer, the Internet has also offered Big Pharma a largely unregulated way to reach the consumer directly – through company websites. For example, if one searches the Lilly blockbuster Prozac on the internet and goes to the manufacturer's website one can take self-diagnostic tests which allow the possibility for the internet user to self-diagnose depression, even if the site includes warnings and disclaimers.

### **Using patient support groups**

In 2000 the Association of the British Pharmaceutical Industry (ABPI) firmly included patient support groups in its promotional strategy “ *The ABPI battle plan is to employ ground troops in the form of patient support groups, sympathetic medical opinion and healthcare professionals – known as stakeholders*” which will lead the debate on the informed patient issue” (Jeffries, 2000). This tactic is well illustrated by the following quote: “*A pharmaceutical company will tomorrow break new ground by encouraging the public to demand that the NHS pay to make available one of its drugs. The campaign, Action for Access, is funded by Biogen and organized by a PR company on its behalf. It will urge multiple sclerosis sufferers to demand their health authorities agree to prescribe beta-interferon on the NHS, a very expensive drug, which can help some sufferers, but not all*” (Boseley, 1999). The United Kingdom Medicines Control Agency subsequently stopped this initiative citing it as unlawful promotion. However Herxheimer (2003) points out that in the absence of adequate independent funding patients organisations and lobbying groups are likely to continue to accept funding from pharmaceutical companies despite the clear ethical issues. He gives as examples the *International Alliance of Patient Organisations* and the *Global Alliance of Mental Health Illness Advocacy*, which are both highly visible and linked financially to Big Pharma.

However some suggest that patient associations are becoming more sophisticated in their interactions with Big Pharma. The Chairman of the Danish Migraine Association is quoted by Medawar (2002) telling of his association's experiences when it refused to take industry assistance in its activities – magazines, lectures and administration. “*The industry, generally assisted by the research doctors, literally created a new patient organization as a substitute for the Migraine As-*

sociation in 1996. This was a bit too blatant to be generally accepted among informed patients and opinion makers, but only because we did not accept the situation gracefully and made the press aware of our situation. .... Luckily we have a growing awareness about the problem.”

Medawar points out that Big Pharma have been successful in presenting their concerns to reach consumers directly as a consumer rights issue, and a potential positive contribution to national health profiles. He suggests that Big Pharma is “gradually shifting the core of its business away from the unpredictable and increasingly expensive task of creating drugs and toward the steadier business of marketing them.”

### **The Push Strategy: Promotion to physicians and health-care professionals**

*“Despite the boom in consumer ads, doctors are still king” (Maguire, 1999).*

However enormous the implication of DTCA of drugs and the budgets devoted to it, physician-targeted promotion is more significant both financially and in terms of eventual outcomes. Komesaroff and Kerridge (2002) state that promotion and marketing to doctors make up a quarter to a third of their annual budgets “... totaling more than \$11 billion each year in the United States alone. There are no comprehensive figures available, but it is estimated that, of this, about \$3 billion is spent on advertising and \$5 billion on sales representatives, while expenditure per physician is believed to be over \$8000.” As mentioned earlier in this article the Canadian Medical Association Journal in 2002 estimated the US promotional spend to be even higher at approximately \$19 billion dollars. This activity includes advertising, gift giving and support for medically related activities such as travel to meetings and support for conferences.

Why do firms spend so much on promotion to doctors? Essentially because they rightly see that doctors are the gatekeepers to the success of individual brands. To quote Barnes (2003) “Prescribing ‘events’ such as a physician swapping one brand for another .... Can make or break a brand’s success.” Doctor-targeted promotion takes a variety of forms:

- Gifts, such as free samples, small stationery (Riccardi, 2002), travel to conferences and educational events, and, some argue, cash (Medical Marketing & Media, 2003; Prawirosujanto 2001; Strout, 2001).
- Sponsorship of conferences and educational events (Moynihan, 2003; Hayes *et al.*, 1990; Komesaroff and Kerridge, 2002).
- The use of key opinion leaders – i.e. senior clinicians and medical educators as speakers at learned conferences Lerer (2002) Burton and Rowell (2003).
- Funding of medical journals through advertising.

Pharmaceutical companies use medical journals to advertise their products, and frequently advertising revenue is the only source of funding of these journals, which are often sent free to doctors. Smith (2003), the editor of the *British Medical Journal*, writes thus of advertising by Big Pharma “To attract advertising these publications have to be read by the doctors whom the advertisers want to reach. So the free publications work hard at making themselves attractive, relevant, interesting, and easy to read – in contrast to journals, which are often delivering complex, difficult to read material of limited relevance.” Davidoff *et al.* (2001) write of a decision among the editors of some of the world’s largest medical journals to adopt a common policy of disclosure of information about the source and validity of articles submitted for publication, and possible conflicts of interest. Hence, for example, contributors to the *British Medical Journal* must disclose any potential conflicts of interest that might arise. This policy does not however apply in the non-medical press and women’s magazines, and many of the world’s broadsheets carry thinly-veiled commercials for medical conditions, such as Revill’s coverage of female testosterone deficiency in the United Kingdom national newspaper *The Observer* in January 2003.

*“ We doctors are shamelessly manipulated by drug companies in all sorts of ways. ..the methods cover the whole spectrum from subliminal to brazen, from little pens that don’t work to pushy reps” (Farrell, 2000).*

## Doctors' responses to Big Pharma promotion

Doctors are unlikely to be undiscerning recipients of advertising and other forms of promotion. Smith (2003) says "*Your opinion may not be bought, but it seems rude to say critical things about people who have hosted you so well.*" He goes on to say that the easy dichotomy of pharmaceutical giants as villains and doctors as innocent victims is over-simplifying the situation. Clearly doctors need to use drugs in order to deliver their services, and it is also reasonable that firms should be allowed to promote their products. "*But surely doctors should be looking also to independent sources of information, and how did we reach a point where so many doctors won't attend an educational meeting unless it's accompanied by free food and a bag of 'goodies'?*"

Separate studies by McInney, Scheidermeyer, Lurie *et al.* (1990), Banks and Mainour (1992) and Chren, Landefeld and Murray (1989) all found that there was a strong correlation between doctors' tendencies to recommend drugs and their receipt of gifts/sponsorship/ non-related payment etc. Studies by Wazana (2000), Chren *et al.* (1989) and Thomson, Craig and Barnham (1994) all show that gifts impact doctors' prescribing practices. Wazana (2000) examined 29 empirical studies of the impact of interactions between the medical profession and Big Pharma. Synthesising these findings certain negative outcomes were found to be associated with interactions with the industry:

- Inability to identify inaccurate claims about medications
- Rapid adoption and prescription of new drugs
- Formulary requests for medications without important advantages over existing listed medicines
- Nonrational prescribing behaviours
- Increased prescribing rates, and
- Prescribing of fewer generics and more expensive new medications at no demonstrated advantage.

Many studies that indicate the advertising rather than clinical evidence alone affects clinical decision-making (Komesaroff and Kerridge, 2002). For example Peay and Peay (1988) found that physicians exposed to advertising are more likely to accept commercial evidence, rather than well-established scientific views. As Lexchin and Mintzes (2002) argue, if advertising results in these negative outcomes with physicians who are more knowledgeable about drugs and can more easily access objective information, "*how realistic is it to believe that consumers will be positively affected?*"

## Why should pharmaceutical marketing practices be of concern?

There are a number of key reasons for concern about the impact of pharmaceutical companies' marketing strategies. These include:

- Drug promotion can be misleading
- The risk of disease mongering
- The increasing costs of drugs within national health systems
- New drugs are the ones most heavily promoted and these are the ones with the least well-understood safety profiles.

## Drug promotion can be misleading

A U.S. congressional inquiry reported that from August 1997 to August 2002 the FDA issued 88 letters accusing drug companies of advertising violations (Gottlieb, 2002). In many cases companies overstated the effectiveness of the drug or minimised its risks. Aitken and Holt (2000) found that the FDA filed violation notices for one in four products supported by DTCA. As discussed earlier the instance of non-compliance with medicines board's requirements for accuracy is even higher in New Zealand. PHARMAC, the New Zealand government's drug purchasing agency, has raised considerable concerns about the impact of DTCA saying that consumers interpret the existence of DTCA as government approval of advertised brands, which leads them to discount potentially important risk information.

## Misleading advertising can lead to unrealistic expectations

There are many instances of inappropriate drug advertising. Healthy Skepticism New Zealand (HSNZ), a publication of the Medical Lobby for Appropriate Marketing, focused on some of the issues relating to promotion of *Viagra* in June 2000. They found that the product claims made were in many cases inappropriate since they did not offer enough clarity. The Pfizer ad in New Zealand was as follows “About 52% of men aged 40 to 70 are affected by erectile dysfunction .....In clinical trials 78% of men reported improvements in their erections. So *Viagra* will work in about 4 out of 5 men.” HSNZ took issue with the ad on the following grounds:

- The 52% figure was inaccurate and misleading and had no basis in fact. It was rather the extrapolation of a very limited but favourable related clinical trial.
- This claim could affect men with confidence rather than medical problems – they argue that “exaggerating the severity and/or frequency of conditions to expand markets has been described as disease mongering”.
- That “will work” was misleading since it might give the impression that *Viagra* would “work well enough to enable successful sex” which was not always true. They point to clinical studies that suggest that the success rate of *Viagra* was in fact 44%.
- They also point out that efficacy in the real world may not equate to the efficacy reported in clinical trials because of halo effects created by enthusiastic specialists.

While patients might be very disappointed because of unrealistic expectations based on advertisements, these are not as serious as what HSNZ see as the irresponsible downplaying of risks. In a much smaller font on the ad the following three sentences are printed in bold: “*You must not take *Viagra* if you are using any nitrate medication including amyl nitrate (poppers). It may lead to a severe drop in your blood pressure, that may be difficult to treat. As sexual activity may be a strain on your heart your doctor will need to check whether you are fit enough to use *Viagra**”. HSNZ take issue with this warning because they feel it is inadequate, because the use of technical terms such as nitrate medication, rather than brand names may mean that those potentially at risk do not recognize the risks; “readers may not realize that the ‘severe drop in blood pressure’ may be a euphemism for death”; and it does not refer to existing evidence of the considerable risks that may exist for some potential users and the number of deaths that have been associated with the inappropriate use of *Viagra*. In 1998 Brooks showed evidence that 69 deaths associated with the inappropriate use of *Viagra* with legitimately prescribed but contra-indicated drugs. HSNZ make reference to a number of studies that show that there are many contra-indications for *Viagra*, and they feel that these contra-indications should be more openly and clearly flagged. For similar issues see also Blondeel (1997), [www.bbc.co.uk/panorama](http://www.bbc.co.uk/panorama) - *Seroxat* (2002), and Oldham (2003).

## Disease Mongering

Thomas (1980) wrote of his concerns about the potentially negative impacts of increased drug and disease promotion. He felt that the constant emphasis on health risk and the promulgation of the view that people are “*fundamentally fragile, always on the verge of mortal disease*” was simply untrue. He suggested that “*The new danger to our well-being, if we continue to listen to all the talk, is in becoming a nation of healthy hypochondriacs, living gingerly, worrying ourselves half to death.*” This view is also held by Mintzes (2002) who gives examples of the direct relationship between exposure to advertising and enrolment in drug regimens that are not always necessary or appropriate. Shapiro and Shultz (2001) argue that the increased public exposure to media advertising and discussion of antidepressants such as *Paxil* (*Seroxat*) and *Prozac* have directly led to the inappropriate prescribing of these drugs to patients whose symptoms do not merit such extreme therapies, a view shared by Medawar (2002).

These views are directly at odds with the reality of pharmaceutical industry practices such as that of increasing brand penetration through identifying new ailments that may be treated by existing drugs (thus extending the brand’s target markets and potentially its sales). This is well illustrated by U.S. advertisements promoting the Pfizer anti-depressant *Zoloft* as a potential solution to PMDD – pre-menstrual dysphoric disorder, which has symptoms not that dissimilar to

menstrual syndrome (PMS). Similarly the BBC reported a story in Sep 2000 of the propensity of U.K. doctors to prescribe *Proxac* for PMS (BBC website Sep 2000).

### **Ever-increasing costs**

Expenditure on drugs has grown faster than the gross national product in all European countries, as in the United States (Ess, Schneeweiss and Szucs 2003). Ess *et al.* (2003) identify the various methods by which European Union member states attempt to control drug costs, chiefly through price fixing or drug budgeting. This parallels the United States where Health Maintenance Organisations and company health schemes already limit their formularies and will not pay for certain drugs<sup>1</sup>. For example both the Californian Health Maintenance Organisation Kaiser Permanente, and the NHS in Britain refuse to reimburse patients for Viagra. Moynihan (2003) also points out that costs have spiraled for drugs, vastly exceeding national rates of inflation. Echoing Medawar's (2002) point, it would seem clear that Big Pharma has decided to harvest its investments in development. At least some of the considerable national expenditures on drugs each year is due to inappropriate prescribing for conditions that do not require drugs – the disease mongering spoken of earlier. Another considerable element of the expenditure is related to prescribing newer more expensive medications where older less expensive medications would be just as good. This would seem to be borne out by Stern and Ehrenberg's (2003) finding that 80% of pharmaceutical marketing managers believed that the easiest way to increase the sales of their drugs was to get existing users to prescribe them more. They argue however that pharmaceutical firms would be better advised to acquire more customers, i.e. generate more occasions for prescribing. Either way the implications for costs are enormous. It is important to note though that increased prescribing is only cost inefficient if medications are prescribed inappropriately. If they are being used appropriately they may save money from other more expensive elements of the health care system, in particular hospital costs.

### **Less known about newer drugs**

Industry analysts note that a higher proportion of the overall budget for newer drugs is devoted to marketing (Cutting Edge, 2003). However, by virtue of their newness, little is known about the potential risks of such drugs once used outside the relatively rarefied circumstances of clinical trials. Difficulties may arise with the drugs once they are used on patients who are using other conflicting drug regimes, or with other illnesses.

### **Current regulation of industry marketing practice**

Having considered the potential risks associated with pharmaceutical marketing as discussed above, one might reasonably wonder what measures/protocols exist to counter such potential risks. Regulation effectively takes two forms: government-based formal industry regulation, and industry self-regulation. Most governments have agencies charged with monitoring the marketing of medicines. In many cases these are wider bodies that also regulate foodstuffs – such as the U.S. Food and Drug Administration. Typically monitoring of marketing practice is one of many briefs for these agencies, and it tends to be reactive in nature. In other words such monitoring as does occur, occurs only in response to complaints, and even then is often very slow and cumbersome. This is often due to limited budgets and the reliance on industry self monitoring/regulation.

Industry self-regulation is typically conducted through national industry bodies such as the Association of the British Pharmaceutical Industry (ABPI), US PhRMA organisation and the Irish Pharmaceutical Healthcare Association (IPHA). These usually have codes of ethics/practice around marketing and promotion. They are often quite forgiving in nature. For example in the case of sponsorship of overseas travel the IPHA has the following to say:

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<sup>1</sup> This is not to suggest formulary limitation is in itself wholly negative, it depends on the selection criteria used to make decisions on whether to include or exclude drugs.

*“Companies may be requested to sponsor the travel expenses of a member of the health professions attending and overseas international scientific conference. The expenses incurred by the delegate in attending such a conference can reasonably be paid to the delegate by the company and this is acceptable. Hospitality extended by a company to a delegate attending an overseas meeting must be reasonable in level and secondary to the major purpose of the occasion at which it is provided. Hospitality must not be extended beyond health professionals” (IPHA, 1999).*

Similarly the ABPI has this to say about members’ involvement in continuing medical education: *“the pharmaceutical industry is also deeply involved in doctors’ continuing education, and helps in training prescribers in the uses and techniques of new medicines. G.P.s and other health professionals would find it difficult to keep up to date with scientific and medical advances without these initiatives”* (ABPI, 2003). They go further in a position paper to say that the ABPI directly complies with UK statutory regulations on the marketing and promotion of medicines.

The US equivalent organization PhRMA adopted a voluntary code of practice for its member organizations in July 2002 that seems to propose the toning down of the extremes of gift-giving and inducements to doctors. However in reading the question and answer section at the end of the code of practice it is clear this is not the case. Gift giving and generous hospitality, and in some cases, fees for endorsement of products, are still very much allowable. It is important to note that in the United States while PhRMA has its own voluntary code, the FDA still actively monitors promotion, though it lacks the resources to monitor more than a fraction of all promotion, and there are mixed views on its efficiency. A critique often leveled at government monitoring systems, such as the U.S. FDA code of practice, is that often the penalty systems are inadequate to the point of being ineffectual.

Similarly the penalties imposed under industry codes of practice could be considered very lenient. For example under the United Kingdom’s ABPI code of marketing practice complaints about infringement can be made by anyone including members of the public. The company has six weeks to respond in writing, with a defense of the issue at hand. This complaint is then considered by a panel of three people with legal backgrounds, on behalf of the ABPI. If the company is found to be in breach of the code of practice they will incur a fine in the order of £1000 (approx \$1670) and be required to give an undertaking to withdraw all offending materials within approximately two weeks. If the breach is judged to be serious, and to “bring the industry into disrepute” then the fine will be more severe, but still relatively small.

This begs the question: Is it appropriate to allow an industry such as Big Pharma to self-regulate in the area of marketing? Should this not be the role of government, or wider industry organs such as the International Chamber of Commerce (ICC)? Taking the ICC role first it is clear that while individual pharmaceutical companies may well be members of the ICC, they do not often adhere to the again voluntary code of marketing practice which states the following about sales promotion for example *“all sales promotions should be legal, decent and honest ... all sales promotions should be so designed and conducted as to avoid causing justifiable disappointment or giving any other grounds for reasonable complaint”* (ICC2002). Would pharmaceutical promotion meet these standards? The evidence of research into the promotion of products such as Viagra, Seroxat/Paxil and Baycol would suggest not. The fundamental issue in the case of industry organization codes (including ICC) is the real absence of sanction. PhRMA’s code of practice is voluntary, as IPHA’s and ABPI’s are, and *“each member company is strongly encouraged to adopt procedures to ensure adherence to this code”* (PhRMA, 2002). It could be argued that such voluntary self-regulatory codes are not designed to ensure accuracy and objectivity, but are instead set up to ‘level the playing field’ among member companies. An examination of the origin of complaints to such bodies indicates that most tend to come from other drug companies (Lexchin, 2003).

## **A way forward**

Clearly there are many aspects to this issue, not least the argument frequently put forward by Big Pharma that they fund the majority of research into often life-saving therapies and are

therefore net contributors to society. There are also obviously the wider philosophical debates about the degree to which societies should be regulated, and issues around defining reasonable profit and appropriate business behaviour which beleaguer many sectors, not just Big Pharma. However despite these elements, I believe that there is an argument for greater vigilance with regard to pharmaceutical industry marketing practice. This may mean decoupling regulation and monitoring from industry bodies and establishing separate bodies tasked with overseeing industry practice. An example of this type of structure is the U.S. Public Company Accounting Oversight Body established by the U.S. government in the wake of the Enron and Worldcom scandals. However it must be recognised that there are critiques of such bodies on the basis that they tend to be funded by industry and often it is difficult to decouple the interests of industry from the overseeing bodies' activities (Rees, 2003).

In addition to increasing the monitoring and policing of Big Pharma promotion, it would seem prudent to increase the awareness and sophistication of the key promotion targets, through increased education about marketing. General consumer education is difficult to achieve, as is daily evidenced by the limited success of public health promotion campaigns such as those around the health risks of smoking. That is not to suggest that it should not be attempted, but it would be unwise to expect it to have immediate and universal impacts. While general consumer awareness may be difficult to achieve, considerable opportunity exists for increasing the knowledge base of those with prescribing powers. A review of the curricula of medical schools, for example, across Ireland and Britain shows that at present there is no education in the area of business and in particular marketing (English Maher, 2003). This should surely be addressed, so that at least doctors, and others with prescribing powers, would understand the techniques and practices to which they will be subjected as practitioners.

Initiatives are being taken to increase awareness of the nature and impacts of pharmaceutical promotion in the United States. Significantly the American Medical Student Association has recently begun a campaign to regulate the relationship between Big Pharma and medical students (Moynihan, 2003). The PharmFree pledge that the American Medical Student Association proposes students sign includes the following "I will make medical decisions ... free from the influence of advertising or promotion. I will not accept money, gifts or hospitality that will create a conflict of interest in my education, practice, teaching or research." The tenor of the PharmFree pledge should be the guiding point for setting standards of practice for pharmaceutical marketing. While it would be facile to suggest that the industry should not promote its products and seek reasonable rewards, given the many issues associated with pharmaceutical consumption, as outlined earlier, it would seem clear that there is need for change in the nature and degree of regulation of that promotion.

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