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Ethical concerns regarding misleading drug promotion/marketing by the pharmaceutical industry

Ayomide Esan, 3rd Year Medical Student and Pharmaware, Queen's University Belfast and Peter Mansfield, Director, Healthy Skepticism Incorporated

Address for Correspondence: School of Medicine, Dentistry and Biomedical Sciences, Queen's University Belfast, 71-73 University Road, Belfast BT7 1NN. Email: aesan01@qub.ac.uk ; peter@healthyskepticism.org

The nature of the relationship between members of the medical profession and the pharmaceutical industry has long been a subject of much debate. This has often focussed on interactions between doctors and representatives of pharmaceutical companies. While doctors occupy a unique position with regards to prescribing medication, this necessitates an ethical duty to keep their knowledge and skills up to date in order to safeguard patient care. Traditionally, the pharmaceutical industry has taken a major role in providing such education through the process of drug promotion. This article discusses, within an ethical framework, the influence that drug promotion has on prescribing practices and its potential for misinformation of medical professionals. Although often unintentional, the effects of such misinformation are detrimental to individual patients, and weaken the healthcare system as a whole. Some of the arguments put forward to suggest the innocuous nature of drug promotion are also addressed in this article, using evidence from psychological research to demonstrate the inevitability of prescribing behaviour being influenced by drug promotion. With this in mind, alternatives to the current situation are explored. J NI Ethics Forum 2008, 5: 42-49

Evidence based prescribing: importance of well informed doctors

In the ever changing environment of healthcare provision, prescribing drugs remains one of the roles reserved within the domain of doctors. Medical training provides an integrated knowledge of the disease processes underlying patients' symptoms, combined with a thorough understanding of the physiological workings of body systems and the complexity of potential drug interactions. Such knowledge equips doctors to make rational decisions as to which drugs best benefit patients with minimum adverse effects. The privilege of prescribing power confers a huge responsibility; doctors must ensure that they act in the best interests of their patients by making well informed and unbiased decisions based on the most recent high quality data. Furthermore, the encroachment of marketplace ideology into healthcare organisation creates a potentially vulnerable population of patients who, as consumers, become viable targets for advertising campaigns. Although the direct advertisement of prescription drugs to patients is currently illegal in the United Kingdom, the easy availability of information over the internet means that it is crucial for doctors to remain well informed so as to provide adequate advice to patients ^[1]. The importance of this task cannot be overemphasised since potent prescription drugs can also be obtained by patients over the internet. Thus the imperatives for continuing professional education by doctors are manifold. Ensuring that they are making the best prescription decisions within the options available to them is an important consideration, especially in a constrained healthcare system with limited resources. This touches on the ethical principles of benevolence, non maleficence, and justice, with the maximising of patient benefit, minimising of patient harm and reduction of waste being the intended goal.

Although completely rational prescribing based on proven clinical evidence is the benchmark to which many aim, in reality this is rarely achievable despite the best efforts of any physician. There are several

factors which influence prescribing behaviour; these have been classified broadly into four main groups as scientific, social, experiential, and patient knowledge based on the findings of several studies. While the biological effects of drugs are an important consideration for prescribers, other pertinent factors such as past experiences of using certain drugs, the cost of drugs, local guidelines, peer recommendations, patient expectations and their ability to comply with therapeutic regimens, have all been identified to act in concert to determine the outcome of the decision making process. In addition, considerations vary between the settings of primary and secondary care [2]. The considerable time pressures faced by physicians mean that useful algorithms must be employed, emphasising a need for good quality data around which to structure a decision making framework. Sources of such data include government regulatory bodies such as the National Institute for Clinical Excellence (NICE), medical organisations such as the British Medical Association and the Royal Pharmaceutical Society of Great Britain, who jointly publish the British National Formulary (BNF), as well as local healthcare trust and hospital guidelines. However the pharmaceutical industry is also greatly involved in the provision of medical education, particularly in the case of drugs that are new to the market about which little information is available to prescribers. In fact a recent survey showed that in Ireland, the pharmaceutical industry is the second most common source of information for the prescribing of new drugs [3].

Pharmaceutical industry led medical education: the dangers of drug promotion

Educational activities undertaken by the pharmaceutical industry take the form of sponsored seminars and meetings promoting new drugs and are often the only source of information available on these drugs. While the provision of information has been valued by some prescribers as helping to widen choices, drug promotion can carry a high risk for the misinformation of recipients. Drug promotion has been defined by the World Health Organization as "all informational and persuasive activities

by manufacturers, the effect of which is to induce the prescription, supply, purchase and/or use of medicinal drugs.^[4] Studies have shown that exposure to drug promotion has an effect on prescribing patterns, which may sometimes result in reduced quality of prescribing^[5-7]. This has been attributed, among other factors, to unintended bias in promotional materials due to the commercial nature of drug promotion. The selective use of information presented to physicians reduces their ability to make weighted decisions based on all the available evidence, resulting in sub optimal usage of potentially useful drugs. This rarely arises as a result of direct corruption and is most often due to confirmation bias resulting from the conflict of interest involved in evaluatory studies on drugs, sponsored by the pharmaceutical companies which produce them^[8].

The harmful effects of drug promotion can also take an indirect form. The inappropriate use of expensive drugs that are incorrectly perceived to be more efficacious than existing cheaper alternatives creates an opportunity cost for the health service, reducing the available resources for the provision of other essential services. Also, the increased revenue generated by altered prescribing practices in response to drug promotion is interpreted by pharmaceutical companies as a direct return on investment and encourages further expenditure on drug promotion, reducing the proportion of the total company budget available for research and development. In the long run this has a negative impact on the size of the pipeline of new drugs to deal with pressing medical problems, resulting in a reliance on drug promotion for revenue generation. Thus a vicious cycle is created and sustained in which drug promotion is required at greater levels to increase market penetration of existing drugs to the detriment of the development of new ones, reducing choice for prescribers and patients^[9, 10].

One of the main arguments in favor of drug promotion has been that it does not necessarily result in a change of prescribing patterns. The scientific training of doctors provides them with the skill of critically

analyzing scientific literature which is considered to protect them from the potentially misleading effects of materials marketing the sale of new drugs. However, current evidence suggests that this is not the case, and there is a discrepancy between the proportion of physicians who consider themselves vulnerable to the persuasive effects of drug promotion [1%] and the proportion of their colleagues considered susceptible [51%], according to the responses given by respondents in a recent survey ^[11]. Various theories have been proposed to explain the influence of drug promotion on doctors. The use of representatives to carry out drug promotion as well as the giving of small gifts such as pens and mugs bearing the logo of specific drugs establishes relationships of a personal nature with physicians, which may serve to increase the risk of unintended bias ^[12]. Psychological studies have demonstrated the impact of suggestion on decision making. When such suggestion is plausible, as is the case in drug promotion, there is an even greater effect on subconscious clinical judgment ^[13, 14]. Rationalising subconsciously driven decisions after they have been made has been proven to be a deep seated characteristic of human nature and thus identifying the reasoning behind decisions is problematic ^[15]. The persuasive scientific arguments of pharmaceutical representatives may not be easily disentangled from other, less rational factors, such as the emotional effects of advertising. This suggests that the only way prescribers can be protected from making biased decisions is if their decision making is based solely on unbiased evidence, indicating that medical education on pharmaceutical products should be sought from more objective sources.

Bucking the trend: proposals for reform

The above recommendation is one that has been proven to be successful in improving the quality of prescribing; in one study, following a policy of receiving no drug promotion by pharmaceutical representatives had a lasting effect on physicians for a period of five years when compared to controls ^[16]. Nevertheless, maintaining such

policies is difficult on an individual level. While the onus of continuing medical education has been placed on individual doctors, the lack of an alternative to pharmaceutical industry derived information on drugs in the busy healthcare delivery setting means that avoiding such information will be difficult without a reform of the current system. Culture has been shown to have a strong effect on prescribing practices, with the therapeutic tradition of different departments influencing the drugs prescribed [2]. This raises the hope that instituting a cultural change where drug promotion is no longer relied on for essential information will be successful. Organisations such as No Free Lunch (www.nofreelunch.org) and Pharmaware (www.pharmaware.co.uk) aim to raise awareness of the importance of physician independence when prescribing and provide information on objective sources of information.

There is also a growing movement to reform the system of medical education on pharmaceutical drugs, spearheaded by the international organisation Healthy Skepticism Incorporated, which has as its mission statement the improvement of health by reducing harm from misleading drug promotion. Included among the proposed reform measures are improved regulation of drug promotion and redesigning the incentives for both health professionals and drug companies. This should help to break the vicious cycle where successful drug promotion leads to increased use of drugs by physicians, further encouraging more promotion. In place of the current patent monopolies exercised by pharmaceutical companies, a system of competitive grants for the processes involved in drug development including research, promotion, advocacy and continuing education has been proposed. This aims to reduce bias through a reliance on publicly accountable funding, with benefits for patients and physicians alike. The reduction of the high stakes involved in drug development and consequently drug promotion will also be beneficial to the long term health of the pharmaceutical industry, despite an initial decrease in profits. Nevertheless, such systematic changes are bound to progress gradually. For the time being, the onus remains on

healthcare professionals to ensure that when educating themselves on pharmaceutical products, they only make use of objective sources, among which promotional materials from the pharmaceutical industry cannot in good conscience be counted.

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