

# Ethical issues concerning the relationships between medical practitioners and the pharmaceutical industry



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RELATIONSHIPS INVOLVING medical practitioners and the pharmaceutical industry raise serious concerns and controversy within both the medical profession and the broader community.<sup>1,2</sup> Within the profession itself views differ sharply, from the conviction that the risks associated with such relationships are minimal to a concern that all contact between doctors and industry involves compromise and should therefore be avoided as far as possible.<sup>3</sup> The relationship between the pharmaceutical industry and the medical profession includes clearly desirable aspects (eg, the cooperative efforts of industry, government and prescribers in trying to achieve quality use of medicines) and less clearly ethically justifiable ones (eg, acceptance of lavish gifts and money for entertainment expenses by doctors).

## Sources of concern

Doctors and the pharmaceutical industry share a number of common interests. For example, both are concerned with encouraging effective and responsible use of existing drugs in treatment and care, monitoring of their use, and innovative research. However, the parties have different emphases and focus on different stakeholders. Doctors are interested primarily in patient care and scientific advance, while industry is interested primarily in commercial outcomes. The primary stakeholder in patient care is the patient, whereas the principal stakeholder in industry is the shareholder. The similarities and differences between participants and their interests create both a need for discourse and the potential for conflict.

The contribution made by industry to medical knowledge and practice has been considerable. The cost of development of a new drug is between US\$300 and \$600 million, most of which is provided by industry.<sup>4</sup> Clinical research is also expensive: last year, in the United States, about US\$6 billion was spent on clinical research, of which 70% came directly

## ABSTRACT

- Medical practitioners and the pharmaceutical industry serve interests that sometimes overlap and sometimes conflict.
- There is strong evidence that associations between industry and doctors influence the behaviour of the latter in relation to both clinical decision making and the conduct of research.
- In view of the risk of compromising relationships with patients and the integrity of the research process, doctors must exercise care in their dealings with industry.
- The basic principles underlying the conduct of doctors with respect to pharmaceutical companies should be openness and transparency.
- Clearly articulated procedures should be developed to deal with specific issues such as travel subsidies, receipt of gifts, sponsorship of conferences and continuing education activities, and dualities of interest arising in clinical and research settings.

**MJA 2002; 176: 118-121**

from industry.<sup>5</sup> The total amount spent on research and development is much larger still.<sup>6</sup>

In spite of these clear common interests and benefits of cooperation, concerns of an ethical nature have been expressed by both the medical profession and the community. There are three main concerns:

- The possibility that associations between doctors and drug companies may serve commercial objectives of industry and acquisitive interests of clinicians rather than legitimate care, educational or research goals, thereby compromising the primary ethical obligation of doctors to patients, dividing the loyalties of doctors and undermining the basic trust on which clinical relationships depend;
- The risk that drug promotion will inappropriately influence doctors' decisions; and
- The danger that industry involvement in research will lead to distortions in scientific evidence and prevent independent assessment of data.

These issues have been considered by professional bodies and other organisations, which have from time to time developed guidelines and codes of conduct for their members.<sup>7-9</sup> There has been disagreement about whether voluntary codes are sufficient or mandatory rules are needed,<sup>10,11</sup> but the self-regulatory model has so far largely prevailed in Australia. Last year, the Royal Australasian College of Physicians released new guidelines<sup>12</sup> and the Australian Pharmaceutical Manufacturers Association

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issued a comprehensive code of conduct that provides detailed guidance to industry on such matters as drug promotion.<sup>13</sup>

### The question of divided loyalties

An “interest” is a commitment, goal or value that arises out of a particular social relationship or practice. The possibility that dealings with drug companies might lead to divided loyalties of doctors, or “conflict of interest”, has been an abiding concern, but identifying such conflicts is not entirely straightforward. One definition refers to “either motives that caregivers have and/or situations in which we could reasonably think caregivers’ responsibilities to observe, judge, and act according to the moral requirements of their role are, or will be, compromised ...”.<sup>14</sup> However, this approach understates the crucial dependence of interests on particular relationships and the need for public processes by which coexisting interests can be evaluated.

It is common for relationships to be associated with several interests. Interests of medical practitioners include:

- patient welfare;
- community welfare;
- pecuniary interests (eg, consultancy fees, share holdings, paid employment);
- advancement of career;
- research grants;
- hospitality;
- participation in research.

When a doctor is engaged in a relationship with a pharmaceutical company, a duality of interests exists. It can not be assumed that such a duality will constitute a “conflict” in each case — this will depend on the particular circumstances, and often not everyone will agree anyway. Dualities of interest are common; conflicts relatively rare. Further, whereas the distinction between the two is sometimes clear-cut, at other times it may be subtle and depend on the nature of the relationship in question and the values of the community within which it occurs. Dualities of interest constitute “conflicts” only when they are associated with competing obligations that are likely to lead directly to a compromise of primary responsibilities. To establish whether a conflict of interest exists it is necessary for the factual details to be declared and for the community to have the opportunity to scrutinise the issues publicly.

### Drug promotion

Promotion and marketing (including advertising, gift giving and support for medically related activities such as travel to meetings) make up a very large part of the activities of drug companies (consuming a quarter to a third of their entire budgets, and totalling more than US\$11 billion each year in the United States alone).<sup>15</sup> There are no comprehensive figures available, but it is estimated that, of this, about US\$3 billion is spent on

advertising and US\$5 billion on sales representatives,<sup>15</sup> while expenditure per physician is believed to be over US\$8000.<sup>16</sup>

### Advertising

Doctors generally perceive the way they practise to be determined by knowledge and evidence, but it appears that they often fail to recognise commercial influences on therapeutic decisions and underestimate the subtle and pervasive effects of pharmaceutical promotion. It is disquieting that some practitioners rely on pharmaceutical company representatives for much of their drug information. Although physicians often deny it, there is considerable evidence that advertising affects clinical decision-making behaviour.<sup>17</sup> Contact with drug company representatives leads to prescribing of their drugs;<sup>18</sup> physicians exposed to advertising are more likely to accept commercial rather than well established scientific views;<sup>19</sup> and drug company advertising is associated with an inability of some physicians to identify wrong claims and a propensity to engage in non-rational prescribing behaviour.<sup>20</sup>

### Gift giving

Gift giving is another widespread drug-promotion strategy. A study from the University of Toronto showed that, over a period of one year, psychiatry residents and interns attended up to 35 meetings and 70 drug lunches and received up to 75 promotional items and US\$800 in gifts (although there was considerable variation).<sup>21</sup> In another study, of medical students, more than 80% had received at least a book and in some cases much more.<sup>22</sup>

Although, as with advertising, physicians deny that gifts influence their behaviour,<sup>23,25</sup> here, too, there is clear evidence to the contrary.<sup>17,25</sup> A survey of 120 physicians in Cleveland, Ohio, showed that those who met with pharmaceutical representatives were 13.2 times more likely to request inclusion of the company’s products in their hospital formulary; those who accepted money to speak at symposia were 21.4 times more likely to do so; and those who accepted money to perform research were 9.2 times more likely to do so. The authors concluded that there is a “strong, consistent, specific and independent” association between physicians’ requests that a drug be added to the hospital formulary and interactions with drug companies.<sup>26</sup>

### Support for travel

There is also evidence that drug company support for travel expenses changes the prescribing behaviour of practitioners.<sup>17,26-28</sup> Among the many studies that have demonstrated such an effect, it has been shown that a physician who accepts money to travel to a symposium is 4.5–10 times more likely to prescribe a company-sponsored drug after such sponsorship than before (even though he or she may believe in advance that prescribing behaviour will not be

affected),<sup>27</sup> and is 7.9 times more likely to submit a formulary request for that drug than a physician who does not.<sup>26</sup>

### **Meeting sponsorship and continuing medical education activities**

Sponsorship of meetings is an important and difficult issue. There are clearly common interests between professional societies, which are usually responsible for organising conferences, and the pharmaceutical industry: the former stand to gain substantial funding from the pharmaceutical industry for their meetings and other activities, while, for the latter, unparalleled opportunities are provided to showcase their wares. On the other hand, choices of speakers and topics at meetings may have important implications for pharmaceutical companies, and, if these are subject to influence from outside the professional society, the kinds of impressions that people go away with may be significantly altered.

Indeed, sponsorship of conferences has been shown to lead to bias in favour of the sponsoring companies' drugs,<sup>29</sup> with increases in prescriptions for sponsors' drugs in the six months after an event.<sup>30</sup> Similarly, pharmaceutical support for continuing medical education (CME) activities leads to increased prescribing of sponsoring companies' products.<sup>21,27,29-31</sup> This occurs even when the course content is controlled by the society or institution and the drugs are referred to by their generic names only.<sup>29</sup>

### **Control of publication and research outcomes**

The effect of drug company sponsorship on research and publications is a major issue that will not be discussed in detail here. Briefly, there are many ways in which research findings can be directed towards producing a desired result,<sup>32</sup> ranging from careful design of a trial and selection of drug doses to selective reporting of results or actual suppression of unfavourable outcomes.<sup>5</sup> The prominence of a publication can be enhanced by paying authors to participate, or publishing non-peer-reviewed material as a supplement in a respected journal.<sup>33</sup> Delays in the publication of unfavourable results are common, and it is speculated that the results of many clinical trials are never published at all.<sup>34</sup>

### **Guidelines for action**

Although opinions differ about whether voluntary guidelines or mandatory rules are the best way to monitor potential conflicts of interest, no professional bodies or institutions have proposed a ban on interactions between doctors and the pharmaceutical industry. Indeed, it is accepted that such a policy would not serve the interests of any party. We feel that the most desirable approach is to develop an amicable relationship that allows healthy criticism and is based on clear, but non-coercive, guidelines. This is the view adopted by the Royal Australasian College of Physicians.<sup>12</sup> We have summarised our key recommendations in the Box.

### **Dualities of interest**

The central principle that should be adopted is that arrangements between physicians and pharmaceutical companies should be open and transparent. Dualities ought to be clarified and clearly declared in the relevant context — to patients, research participants, hospital committees, and so on. Whether they constitute conflicts should not be left to the individuals concerned to decide, but to a process of informed public debate within the setting in which the duality arises. Where conflicts appear likely, special procedures should be devised to avoid unacceptable outcomes.

### **Drug promotion, including acceptance of gifts and travel support**

Ideally, drug promotion should be restricted to the dissemination of well-founded data about specific products. This would ensure reduction of costs of pharmaceuticals to the consumer as well as reassuring the community about the independence of physicians, restricting excessive claims about the effectiveness of drugs and ensuring unbiased assessment of evidence.

Benefits received from pharmaceutical companies should leave physicians' and scientists' independence of judgement unimpaired. Various levels of advice have been advanced to medical practitioners about accepting gifts. These range from blanket rejection, to a gradient of moral acceptability based on cost, to the principles that gifts should not be excessive and should not influence decision-making, to the test of whether the recipient would be willing to have the arrangements publicly known.

We feel that the safest general principle for practitioners to adopt is that they should err on the side of rejection of gifts, even those of trivial value. Support for travel to meetings (including conferences organised by professional societies and CME courses) should be restricted to those making formal contributions. Entertainment expenses should not be lavish, although it is recognised that ideas about what constitutes "lavishness" vary according to one's point of view. Access of drug company representatives to students and health services should be limited. We believe that there needs to be a cultural shift towards a lesser

#### **Key recommendations**

- Dualities of interest should be publicly declared and examined for the presence of a conflict.
- Acceptance of gifts should be kept to a minimum.
- Non-service-oriented gifts, including items of trivial value, should not be accepted.
- Entertainment should not be lavish.
- Support for travel should be restricted to those making formal contributions to meetings/conferences.
- Meetings should be organised by an independent committee.
- Research and publication should be guided by scientific and ethical rather than commercial values.

expectation of entertainment, grand dinners, receptions and free food in association with conferences and symposia. The question of support for spouses and partners is an important one. Many people would agree that it is inappropriate under any circumstances. Where there is any doubt, exceptions should be discussed with institutional ethics committees.

### Sponsorship of meetings

Full disclosure of commercial sponsorship of meetings should be made. Sponsorship should always be provided through independently organised scientific committees; speakers should indicate dualities of interest at the time of presentation; and sources of commercial funding should not influence scientific, educational or public policy decisions of the professional body.

### Research

In cases where research projects are being funded by the pharmaceutical industry, the overriding principle is that the values of science and clinical medicine should prevail over commercial imperatives and monetary values. Elimination of bias in research and publication is a large topic, however, and will not be discussed here. We feel that this is an issue of major public importance that needs to be actively addressed by the medical profession in consultation with consumer organisations, government and the pharmaceutical industry.

### Conclusions

The current pattern of relationships between doctors and the pharmaceutical industry is the outcome of a long-established culture in which gratuities, gifts and the like are both expected and provided. As a result, change will require a substantial shift in attitudes and values and thus is likely to be slow. Research into the expectations of stakeholders and the impact of the various practices discussed may contribute fruitfully to community debate.

In reviewing a number of the issues concerning the relationships between medical practitioners and the pharmaceutical industry, we have tried to emphasise that benefits received from pharmaceutical companies must leave the independent judgement of physicians unimpaired and that arrangements between physicians and pharmaceutical companies ought to be open and transparent. The overriding principle should be a firm belief that the values of science and clinical medicine must prevail over commercial imperatives. If these simple guidelines are followed, we feel that much progress will be made towards allaying the concerns of both the community and the medical profession.

### Competing interests

None declared

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scientific article published on 01 February 2002. edit. instance of. scholarly article. 1 reference. stated in. Europe PubMed Central. PubMed ID. 11936308. reference URL. [https://www.ebi.ac.uk/europepmc/webservices/rest/search?query=EXT\\_ID:11936308%20AND%20SRC:MED&resulttype=core&format=json](https://www.ebi.ac.uk/europepmc/webservices/rest/search?query=EXT_ID:11936308%20AND%20SRC:MED&resulttype=core&format=json). retrieved. 9 December 2019. title. Ethical issues concerning the relationships between medical practitioners and the pharmaceutical industry (English). Clinical Ethics. RELATIONSHIPS INVOLVING medical practitioners and the. pharmaceutical industry raise serious concerns and. controversy within both the medical profession and the. broader community. 1.Â institutions have proposed a ban on interactions between. doctors and the pharmaceutical industry. Indeed, it is. accepted that such a policy would not serve the interests of.