Winds of change: growing demands for transparency in the relationship between doctors and the pharmaceutical industry

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ABSTRACT

- The relationship between medicine and the pharmaceutical industry in the United States is undergoing rapid and momentous change; US Senator Grassley has alleged inadequate disclosure of earnings from industry and lack of acknowledgement of conflicts of interest by leading academics.
- This article is based on the premise that it is not the relationship per se that is the problem, but rather how that relationship is enacted.
- The influential 2008 report of the Association of American Medical Colleges (AAMC) has provided detailed recommendations on appropriate interactions between academic physicians and industry (eg, proscribing receipt of gifts including travel support, and proscribing speaking at industry-sponsored educational programs). Contrary to expectations, there has been widespread acceptance of such guidelines.
- In Australia, details of all industry-sponsored educational events are now listed on the Medicines Australia website.
- Australian doctors have no alternative but to drastically improve the transparency of their interactions with industry, both in terms of the remuneration received and disclosure of potential conflicts of interest.
- Australian universities should seriously consider developing recommendations similar to those of the AAMC.

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Most Australian practitioners may be unaware of the rapid and momentous changes currently occurring in the United States in the relationship between the medical profession and the pharmaceutical industry. There is a high-profile public discourse being played out in the pages of the *New York Times* and the *Wall Street Journal*, major scientific and medical journals, and in the US House of Congress. It is a discourse that will inevitably influence Australian practice, and was echoed in a recent editorial in this Journal.[1]

Medicine is facing a credibility problem of unheralded proportions. While the spotlight of public disapprobation in the US has focused on a number of leading figures (and, to my own dismay, a number of prominent academic psychiatrists), it is an issue for the whole profession.

The recent highly publicised "outing" of details of the relationship between medical practitioners and the pharmaceutical industry has arisen largely from two sources: US Republican Senator Charles Grassley of Iowa; and a series of articles in the medical press.[2] Grassley has claimed that there are exorbitant and opaque relations between some senior US academics and industry. The allegations relate to the failure of academics to accurately disclose their earnings from the pharmaceutical industry to their respective universities, and a lack of disclosure of conflicts of interest. In March 2008, Grassley and US Democrat Senator Kohl of Wisconsin introduced the "Physician Payments Sunshine Act of 2008", to mandate disclosure of remuneration to doctors. This act has yet to be passed, although it should be noted that such disclosure is already legislated in a number of US states.

This article is based on the premise that it is not the relationship between medical practitioners and the pharmaceutical industry per se that is the problem, but how that relationship is enacted. While some argue that the medical community should divorce itself completely from industry, this is unrealistic. Without private pharmaceutical companies, few innovative medications would have been developed for use in clinical practice. There is no doubt, though, that the relationship between the medical profession and industry is currently dysfunctional. The challenge is how to transform this relationship into one based on integrity and transparency.

There are few, if any, analogies for the relationship between the medical profession and the pharmaceutical industry. Industry develops medicines to be used by patients, but (in most cases) is unable to advertise or sell directly to these patients; rather, marketing occurs via intermediaries — the doctors who prescribe and the pharmacists who dispense.

In the words of Moynihan: "Twisted together like the snake and the staff, doctors and drug companies have become entangled in a web of interactions as controversial as they are ubiquitous".[3] He argues forcefully for recognition of such "entanglement", and the imperative for "disentanglement". However, there are also substantial dualities of interests between the profession and industry, as well as the potential for major conflicts of interests.[4]

The relationship between doctors and industry

Contact between the medical profession and the pharmaceutical industry is extensive. An overview of studies on the effect of contact between doctors and the pharmaceutical industry found that having meetings with pharmaceutical representatives was significantly associated with both requests from physicians for adding drugs to hospital formularies, and to changes in their own prescribing practice.[5] Attending industry-sponsored educational events and accepting funding for travel or accommodation for educational symposia were associated with increased prescription rates of the sponsor's medication. Receiving honoraria for speaking and engaging in industry-sponsored research were also associated with requests for adding the company's product to formularies.

Gifts

These vary from pens and notepads to sponsored travel and accommodation for attending national and international meetings. The impact of receipt of even small gifts has been emphasised.[6] Drawing from social science research, Brennan and colleagues commented on the general human impulse to "reciprocate" for even small gifts, and that those receiving such gifts are often

unable to remain objective as they "reweigh information and choices in light of the gift". Further, they stated that "... the expectation of reciprocity may be the primary motive for gift-giving".[6]

"Key opinion leaders"

These are senior doctors (usually academics) whose opinions are considered influential in determining both diagnostic and therapeutic practice. Undoubtedly, significant resources are lavished on this group, and those targeted by Senator Grassley's inquiries would be considered within this category. Furthermore, in media reports on new medications in which such a "key opinion leader" was cited, half of such experts had financial ties to industry, and in only a third of these cases were those ties acknowledged.[7]

Ghost writing

There has been recent concern about the apparently common practice of "ghost writing". A damning exposé of this practice used documentation from legal proceedings concerning the anti-inflammatory agent rofecoxib to provide the hitherto best-documented case history of the relationship between the pharmaceutical industry, medical publishing companies and academic clinicians.[8] This report described pharmaceutical company employees working either independently or in collaboration with medical publishing companies in preparing manuscripts on clinical trials, and subsequently recruiting external academically affiliated investigators to be the publication "authors". These recruited academic authors were frequently given first or second authorship positions. For scientific review articles, similar processes were documented, with the academic recruits frequently being the sole authors and, moreover, being offered honoraria for their participation. While industry financial support was acknowledged in most of the clinical trial reports, this was reported in only half of the review articles. As discussed by the authors of the report, it is unlikely that such practices differ from those of other companies and other products.[8]

How are the various bodies responding?

University medical schools

In 2008, the Association of American Medical Colleges (AAMC) released a formal report on industry funding of medical education.[9] This thoughtful and robust report began with an acknowledgement of the appropriateness of a partnership with industry, yet also the need to manage this: "The fault lies not only with industry; the acceptance, indeed the expectation of such financial incentives by academic professionals and their institutions has encouraged these practices."[9]

This report recommended clarity about the extent to which interactions with industry are prohibited, and commended the necessity for educational programs on the relationship with industry for students, trainees and teaching faculty. It proscribed receipt of gifts, cautioned on the distribution of samples, and restricted access of pharmaceutical representatives. Strikingly, the report strongly discouraged the involvement of faculty in industry speakers bureaus, and proscribed accepting payment for attendance at industry-sponsored meetings and acceptance of gifts at such events. Furthermore, it stated that industry-supplied food and meals should be considered as gifts and therefore not be accepted. Acceptance of travel funds was proscribed, as was allowing written or oral presentations to be ghost written. Those involved in decisions about purchases of pharmaceuticals or devices were required to declare all conflicts of interest.[9]

What has been the impact of this report (and others) on clinician behaviour in the US? A recent commentary described a surprisingly widespread acceptance of these major shifts in practice.[10] Contrary to the fears of many, no significant movement of academic faculty out of those medical colleges with strong conflict-of-interest policies was observed.[10]

Pharmaceutical industry organisations

In Australia, the umbrella industry representative body, Medicines Australia, published the 15th edition of its code of conduct in 2007.[11] For the first time, and under the direction of the Australian Competition Tribunal, this code detailed mandated website disclosure of all industry-sponsored educational and marketing activities in Australia and the associated costs (http://www.medicinesaustralia.com.au/pages/page136.asp), although, at this stage, not disclosure of the names of clinicians receiving remuneration. This would appear to be the first national mandated detailing of such activities, and has revealed that about 30 000 such events occur each year, involving at least 800 000 attendances and costing about $60 million per annum, of which the hospitality cost (food, beverages, travel and accommodation) is about $32 million.

What are the options for the Australian medical profession?

Self-regulation by the medical profession has been largely ineffective, despite the best of intents and the development of professional guidelines such as those of the Royal Australasian College of Physicians.[4] This is a problem for both industry and the profession. We now have a major credibility problem with the public; it is an issue of trust. If we do not regulate ourselves, others such as governments or the courts will, and the outcomes of that may not be palatable to doctors.

The central principles of the relationship must be integrity and transparency. Inadequacies in disclosure have been at the centre of recent scandals in the US. Should there be full disclosure, as proposed by Senator Grassley? The ground is already moving rapidly under our feet. A number of US companies have recently decided to publicly detail all remuneration to clinicians, and this may well happen here. In Australia, all promotional and educational events are disclosed under the terms of the 2007 Australian Competition and Consumer Commission authorisation of the industry voluntary code of conduct, though clinician payments are as yet not required to be reported.

We have no alternative but to drastically improve the transparency of the relationship, both in terms of remuneration received and disclosure of any potential conflicts of interest (in all publications, media statements and guidelines[1]).

However, if we go down the route of disclosure of earnings from industry, questions remain. First, should this be in broad terms (such as a generic declaration of remuneration from activities such as advisory boards, consultancies, honoraria for speaking engagements, sponsored travel and/or accommodation to meetings, involvement in industry-sponsored trials, payment for publications written with industry, retainers, or shares in pharmaceutical

companies) or should actual dollar earnings be disclosed? I believe that we will inevitably need to declare actual earnings, and should do so soon, but I accept that this may be too great a demand for the profession at this point in time. Second, to whom should such details be provided? To the public via websites, such as that of Medicines Australia? For clinicians, to the relevant professional bodies? For academics, to university administrators?

While the details of such disclosure will need to be determined, it is clear that we must expeditiously formalise a relationship of integrity and transparency between the medical profession and the pharmaceutical industry. Australian universities should seriously consider developing detailed recommendations such as those of the AAMC, and other medical bodies, such as the professional colleges, need to address the proposals of the AAMC report. The credibility and destiny of medicine in this country are in our hands.

Competing interests

With permission from Oxford University Press, some of the material used in this article has been drawn from: Mitchell PB. Psychiatrists and the pharmaceutical industry: on the ethics of a complex relationship. In: Dudley M, Silove D, Gale F, editors. Mental health and human rights. Oxford: Oxford University Press, 2009. In press. In the financial year 2007–08, I was paid a total of $6500 for lecture honoraria, consultancies and advisory board membership from pharmaceutical companies (AstraZeneca, Eli Lilly and Pfizer). I also received travel support to attend an international scientific forum at which I gave an invited lecture in a symposium in the main program of the meeting. I have not been a member of a pharmaceutical company advisory board since early 2008. I have never owned stocks in pharmaceutical companies, nor received retainers. I have been a site investigator for a number of industry-sponsored trials, the most recent being in 2004. I have also received remuneration from state and federal health departments for various committee memberships, including 3 years serving on the Australian Drug Evaluation Committee.

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