

Postprint

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'Interests' in medicine and the inadequacy of disclosure

Ian Kerridge* (2012)

*Royal North Shore Hospital, Sydney, Australia, and Centre for Values, Ethics and the Law in Medicine, School of Public Health, University of Sydney, Australia

Author Address:

Ian Kerridge, Centre for Values, Ethics and the Law in Medicine, Medical Foundation Building, K25, University of Sydney, Camperdown, Sydney, NSW 2006, Australia. Email:

ian.kerridge@sydney.edu.au

Many papers published in the academic press sink without a trace, making no impression on clinical practice, health policy or public discourse. While the narrative review of melatonin-based therapies for depression published in the Lancet by Professor Ian Hickie and Associate Professor Naomi Rogers (2011) is unlikely to generate significant changes in clinical practice, it has generated enormous professional and media debate about the extent and impact of conflicts of interest in medicine arising from the relationships between health professionals and the pharmaceutical industry.

In the disclosure accompanying the review, which highlighted the potential worth of the drug agomelatine, manufactured by Servier, both authors disclosed financial and professional links with Servier. The responses to this review, and to the disclosures made by the authors in the Lancet, on health media websites, in the lay press and in social media, have been largely critical – making either empirical claims, that the authors misreported the tolerability and/or efficacy of agomelatine, or moral claims, that the authors were conflicted or biased, had not adequately disclosed the extent of their interests, or that they or Elsevier (the publisher of the Lancet) may have gained some benefit from the publication (Barbui and Cipriani, 2012; Carroll, 2012; Dunlevy, 2012; Griffiths, 2012; Howland, 2012; Jureidini and Raven, 2012; Lloret-Linares et al., 2012; Serfaty and Raven, 2012). In a spirited response, the authors defended both their analysis and their professional ethics, arguing that they had appropriately attended to the processes of disclosure required by the Lancet for all contributors (Hickie and Rogers, 2012).

That Hickie (in particular) is entangled in a web of competing interests would seem beyond question. In this regard it is likely, however, that he is no different to many academic researchers, clinical psychiatrists, directors of research centres (who are generally expected to create and sustain links with industry and forge public-private partnerships) and physicians from other disciplines (Cosgrove et al., 2009). Indeed, one would expect that, as a leading academic, researcher, clinician and public

advocate, Hickie would have a number of competing interests, as every social role has associated with it a collection of moral, social and professional imperatives which one assumes when one adopts that role. Likewise, in many ways, it is not surprising that he has extensive ties with the pharmaceutical industry.

Psychiatrists and psychiatry have long been the focus of many such concerns, being caught up in disputes surrounding the impact of commercial interests on the definition and diagnosis of mental illness (Angell, 2011; Pileckie et al., 2011), medical publishing (Angell, 2004), drug promotion (Perlis et al., 2005), non-disclosure of pecuniary conflicts of interest (Harris and Carey, 2008) and ghostwriting by commercial sponsors of research (Lacasse and Leo, 2010). Opinions leaders, academics and leading researchers, in particular, would seem particularly likely to have extensive relationships with industry. A recent review of disclosures made by panel members of the Diagnostic and Statistical Manual of Mental Disorders, fifth edition (DSM-5) task force found that 69% of the DSM-5 task force members report having financial ties to the pharmaceutical industry, with 67% of the panel for Mood Disorders, 83% of the panel for Psychotic Disorders and 100% of the panel for Sleep/Wake Disorders having ties to the pharmaceutical companies that manufacture the medications used to treat these disorders or to the companies that service the pharmaceutical industry (Cosgrove and Krinsky, 2012).

That ‘everyone does it’ is, of course, not a sufficient moral justification for any behaviour. What is necessary, both in this case and with regard to the issues surrounding relationships with industry more generally, is to establish whether any of these divergent interests constitute a genuine conflict of interest (COI), such that one’s commitment to research, teaching, patient care and the design of policy in mental health is distorted or subverted. This is, rightly, a matter both for considered personal reflection and for the judgement of the relevant community of stakeholders – in this case, both the psychiatric community and the Lancet.

Relationships between medical professionals and the pharmaceutical industry have long been a source of intense debate, largely because of concerns that such relationships may increase the costs of health care, create ‘gift relationships’ of reciprocity and mutual obligation (Katz et al., 2003), encourage prescribing of medicines that are either not needed or are more expensive than existing alternatives (Spurling et al., 2010), and ultimately subvert the (proper) goals of medicine, medical education and medical research (Bekelman et al., 2003; Komesaroff, 2010), in large measure by creating a COI. However, while we often use the term ‘COI’, this is not always easy to define or recognize and its management is often not straightforward. While all would agree that competing interests (which in general terms can be understood as a situation where two or more interests are contradictory and compel incompatible outcomes) should be declared, the notion that this is sufficient to expunge the possibility of bias and that responsibility for assessing the validity and reliability of research results, practice recommendations or prescribing decisions lies with readers or with patients/consumers, is both naïve and morally inadequate.

There are a number of problems with relying on declaration for the management of COI. First, while transparency and open disclosure are important, simple disclosure of one’s interests does nothing to reduce the prevalence of pecuniary and non-pecuniary conflicts of interest or the potential harms and biases that accompany them. (If I intend to set fire to a public building, my declaration that I will do so before lighting the match does not make the action right nor minimizes the impact of that action.) Second, there is at least the possibility that the ‘noise’ created by mandatory declarations (at scientific meetings and in the press) may actually obscure the meaning and extent of the relationships that researchers, physicians and policymakers have with industry. Third, we know from the available empirical literature that physicians, researchers and students are influenced by contact with industry but believe, wrongly, both that they are not influenced by their interactions with industry, and that they are able to detect and manage bias and influence (Kerridge, 2011).

Clearly, therefore, what is necessary is not simply a requirement of disclosure, but rigorous, transparent and professionally accepted processes for assessing and managing competing interests. This is no small undertaking as it relies on the relevant community(s) establishing guidance and processes for determining what relationships are, and are not, acceptable, and for clarifying the circumstances in which, and how, such competing interests should be managed, either through declaration alone or through collaboration, consultation, abstention, delegation, divestment or separation. The problem here is that while journals, industry and professional bodies have now largely established processes around the declaration of interests, there is very limited guidance regarding the assessment of competing interests or the appropriate strategies for managing specific circumstances where conflicts of interest arise. There are likely to be many reasons why this is the case:

In part, it may be because of a genuine reluctance to acknowledge the degree to which medicine operates in a commercial context;

- It may be because each party assumes it is the responsibility of the other;
- It may be because it relies on the profession giving up a degree of its professional autonomy (at least with regard to the setting of standards);
- It may be because it requires professionals making judgements about one another's personal and professional behaviour (which is never straightforward); and
- It may be because there is very little professional or public agreement regarding the relationships that health professionals should have with industry.

Despite these challenges, if one accepts that Hickie and Rogers (2011) had made a full and open disclosure, and there is no reason to believe otherwise, it is then the task of the Lancet and of the professional and academic community to determine both whether the existence of these multiple competing interests had the capacity to corrupt decision-making and analysis and what should be done about them. This requires both a degree of humble introspection on the part of the investigators in accepting the commission to write the review in the first place, and a commitment to public discourse and to the development of a clear and equitable process on the part of the journal and the profession. If we are to take conflicts of interest in medicine seriously, and if we wish to avoid disputes about conflicts of interest filling the pages of our journals and lay press, then we should turn our attention to establishing what aspects of the relationships with industry are both necessary and appropriate and start looking beyond disclosure.

Declaration of interest

IK is not employed by, nor receives support from, any pharmaceutical, pathology or biotechnology company for teaching, research, education, travel or professional consultation. Nor does he own shares in any such company. As a staff haematologist, IK actively recruits patients to relevant clinical trials sponsored by pharmaceutical companies including, at present, Amgen Inc., Bristol-Myers Squibb, Celgene, Janssen Pharmaceutica, Onyx Pharmaceuticals and F. Hoffmann-La Roche Ltd. He has received project grant support from the National Health and Medical Research Council to investigate drug policy and the relationships between the pharmaceutical industry and medical professionals, has made submissions to Medicines Australia regarding the revisions to their Code of Conduct and he is a member of the Royal Australasian College of Physicians Ethics Committee. IK is not a psychiatrist and knows little about melatonin-based therapies.

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