Dear ACCC Committee members,

I am, and have been since 1983, a full-time practicing clinical medical oncologist in both public and not-for-profit private university-based teaching hospitals.
Over this time I have observed closely as the influence of pharmaceutical companies on the 'education' of doctors, the direction and design of clinical research and the practice of medicine in Australia has steadily increased. It has reached a point now where a new culture of entitlement has developed amongst the medical profession, and most worryingly amongst the younger generation. I believe that there is significant observational and research evidence that this is now seriously eroding the independence and integrity of the profession and adding large and often unnecessary costs to our health budget.
Close relations between physicians and the pharmaceutical industry can be very beneficial for the medical profession and for society. However, as with all relationships between private enterprise and those with control over public spending, they must be open and transparent.
I am an Adjunct Clinical Associate Professor in the Department of Medicine at AMREP and Cabrini Hospital, Monash University, Melbourne, and have published a number of peer-reviewed papers on this topic which I attach. I gave sworn evidence to the Federal Court in 2006 on behalf of the ACCC in the hearing challenging the ratification of the proposed 16th revision of Medicine Australia's code of conduct that led to the Court, under Justice North, forcing Medicines Australia to amend its code and release 6-monthly aggregate reports of its spending on marketing to the medical profession. I was then part of a review panel invited to give submissions that led to the 17th Revision and set a timetable for medicines Australia to implement a system of full transparency for all individual members of the medical profession.
As Professor Ken Harvey has stated, at the very least 'these activities can encourage conscious or unconscious reciprocity by the recipients which can manifest itself in uncritical acceptance, overprescribing and use of expensive new company products and underutilisation of more cost-effective drugs and medical devices.'
More importantly however, these activities and largely concealed relationships have been shown to distort published medical evidence by influencing how studies are designed and conducted, by influencing

which studies are published and which are not, and which results and side-effects in the published studies are emphasised and which are not. This can have the overall result of "stacking the deck" in favour of unproven new and expensive treatments which can also have undeclared and serious toxicities. It has also been shown to lead "key opinion leader" doctors to be more willing to advocate for certain treatments over simpler and less expensive treatments when adequate robust evidence is lacking. This advocacy and “control of what becomes medical evidence” by, and on behalf of, the pharmaceutical industry can extend to these expensive, unproven and potentially toxic treatments being put into very influential documents. These documents include current clinical guidelines reviews for doctors in areas ranging from childhood and adult psychiatry to diabetes to arthritis and to cancer. The cost implications of these distortions for our health system, which will continue to be under ever increasing pressure to meet the treatment aspirations and expectations of an ageing population, are very significant indeed.
I attach recent research emphasized the crisis that has developed in clinical medicine in Australia, and worldwide, with this gradual erosion of the autonomy, independence and integrity of the medical profession. We in Australia need a system that strikes the right balance between encouraging innovative research and development and maintaining transparency and accountability. This 18th Revision of the Medicines Australia Code of Conduct is an opportunity to restore that balance and make changes that will help us maintain an effective and cost-efficient health system for Australia.

The whole basis of the democratic capitalist system that we operate under is that vigorous competition is fundamental to its effective and efficient running. This requires the maintaining of the delicate balance between allowing full opportunities for innovations and entrepreneurship to flourish whilst at the same time preserving vigourous oversight of transparency and accountability. We physicians have the power and ability to directly spend vast amounts of public monies on treatments and scripts and like all workers with access to public monies, it is not appropriate for us to have an “opt-in, opt-out” system for transparency in our relationships with the businesses that stand to make vast amounts of profits from our treatment decisions. Our treatment decisions should be based on our interpretation of the best evidence as it relates to our patients and on nothing else. We continue to see over and over again in our society what happens to members of the public when oversight of company finance statements fails, when oversight of the conflicts of

interest of politicians or financial planners fails and many other similar examples of the implications of lax and inadequate oversight. The vast majority of any profession with access to public monies have nothing to hide and always know that they can pass the “How would I feel if this was on the front page of the SMH test?’ There is no ‘opt-out’ available for filing one’s tax return or for having one’s car registration available to the police for tracing of speeding cars or for breathalysers or for providing a police report to potential employers or many other examples. It is a simple task for local and multinational pharmaceutical companies, six of whom are in the world’s 50 most profitable companies, to provide the transparency and accountability that we all need to have full confidence in the integrity of our health system. The vast majority of the medical profession know that they have nothing to fear from this relatively straightforward implementation by Medicines Australia.

The ACCC has served Australia well, including with its past adjudications on the Medicines Australia Codes of Conduct.
We in Australia depend on , and look forward to, the ACCC continuing to be fair, forensic and fearless in its adjudications on our behalf.

Yours Sincerely,
Ian Haines FRACP, FAChPM
Adjunct Clinical Associate Professor of Medicine,
AMREP Dept of Medicine,
Monash University,
Melbourne .

And

Medical Oncologist and Palliative care Physician,
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Research enterprise

Are self-regulation and declaration of conflict of interest still the benchmark for relationships between physicians and industry?

Ian E Haines and Ian N Olver
Med J Aust 2008; 189 (5): 263-266.

Abstract

- Potential conflicts of interest do not imply wrongdoing, but can create bias, distort decision making, and create a perception that practitioners are being “bought “or “bribed” by industry.

- Transparency alone may not be sufficient to erase the doubts created when authors of clinical practice guidelines or editorials declare potential conflicts of interest. Can the subconscious obligation for reciprocation that exists when gifts are offered and accepted be fully negated?

- Analyses of published clinical cancer research studies have found a positive association between pharmaceutical industry sponsorship and reporting of positive outcomes, manipulation of clinical trials, and hiding of “preliminary data sets”. More problematic is the issue of clinical researchers leaking preliminary results to the investment industry.

- Influential literature reviews and treatment guidelines have been associated with widespread declarations of conflict of interest.

- Some potential solutions are: regulating pharmaceutical companies to declare all gifts to clinicians, or ban such gifts; for clinicians to carefully declare potential conflicts of interest or to provide pro bono advice without accepting industry sponsorship; and for all gifts and payments from industry to academic physicians to be coordinated by an independent review committee.

- Journals should only allow reviews, editorials, guidelines and opinion pieces to be written by those without significant conflicts of interest.

Perspectives

Time to mandate data release and independent audits for all clinical trials

Ian E Haines and George L Gabor Miklos
Med J Aust 2011; 195 (10): 575-577.
doi:
10.5694/mja11.10599

As a condition of publication of phase III clinical trials, medical journals should insist on the release of all raw data and a written independent clinical audit

Eur J Clin Invest. 2013 May;43(5):469-75. doi: 10.1111/eci.12074. Epub 2013 Mar 25.

Undue industry influences that distort healthcare research, strategy, expenditure and practice: a review.

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Abstract

BACKGROUND:

Expenditure on industry products (mostly drugs and devices) has spiraled over the last 15 years and accounts for substantial part of healthcare expenditure. The enormous financial interests involved in the development and marketing of drugs and devices may have given excessive power to these industries to influence medical research, policy, and practice.

MATERIAL AND METHODS:

Review of the literature and analysis of the multiple pathways through which the industry has directly or indirectly infiltrated the broader healthcare systems. We present the analysis of the industry influences at the following levels: (i) evidence base production, (ii) evidence synthesis, (iii) understanding of safety and harms issues, (iv) cost-effectiveness evaluation, (v) clinical practice guidelines formation, (vi) healthcare professional education, (vii) healthcare practice, (viii) healthcare consumer's decisions.

RESULTS:

We located abundance of consistent evidence demonstrating that the industry has created means to intervene in all steps of the processes that determine healthcare research, strategy, expenditure, practice and education. As a result of these interferences, the benefits of drugs and other products are often exaggerated and their potential harms are downplayed, and clinical guidelines, medical practice, and healthcare expenditure decisions are biased.

CONCLUSION:

To serve its interests, the industry masterfully influences evidence base production, evidence synthesis, understanding of harms issues, cost-effectiveness evaluations, clinical practice guidelines and healthcare professional education and also exerts direct influences on professional decisions and health consumers. There is an urgent need for regulation and other action towards redefining the mission of medicine towards a more objective and patient-, population- and society-benefit direction that is free from conflict of interests.