Dear Sir/Madam

Please find attached, version 1 of an article that I submitted for Publication to Australasian Psychiatry, a journal of the Royal Australian and New Zealand College of Psychiatrists. This article was published in the Journal in June 2014 as, "*To see or not to see, that is the question: can public disclosure really improve transparency between medicine and the pharmaceutical industry*". In the article, I make the point that funding of health professionals for the purpose of pharmaceutical research should be included in the Transparency Model. This is by far the largest area of payment made to health professionals by the Pharmaceutical Industry. There is irrevocable evidence that Pharmaceutical funding for research biases the results of research. My argument is that the reporting of payments for research would help health professionals understand the linkage between medicine and industry and enable them to exercise their judgement in interpreting research results. By contrast, the reporting of all the small payments will only serve to obscure the larger payments. The published article can be accessed as follows:

Smith, G (2014) To see, or not to see, that is the question: can public disclosure really improve transparency between medicine and the pharmaceutical industry. *Australasian Psychiatry*; 22: 281-284.

Regards
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To see, or not to see, that is the question: can public disclosure really improve transparency between medicine and the pharmaceutical industry?

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Abstract

Objective: To critically review the potential effect of the public reporting of pharmaceutical company payments to healthcare professionals on the relationship between medicine and industry.

Method: This review is based on an examination of the 'Transparency Model' put out recently for consultation by Medicines Australia and of public reporting requirements currently operative overseas, particularly in the USA and the Netherlands.

Results: Public reporting in itself will neither sharpen the boundaries between medicine and the pharmaceutical industry nor restore public confidence.

Conclusions: Focusing on payments for clinical research and on the larger payments to healthcare professionals would lead to a better understanding of the interplay between science and marketing.

Key words

Pharmaceutical, industry, payments, disclosure, research

Introduction

Medicines Australia is the industry body representing the majority of the major pharmaceutical companies in Australia. Its Code of Conduct sets the standards for the ethical marketing and promotion of pharmaceutical products, including standards for the relationship with healthcare professionals. The Code, first established in 1960, has been revised on a regular basis.

In 2007, in response to community concern about the potential influence of industry marketing on professional practice, the Australian Competition and Consumer Commission (ACCC) placed disclosure requirements on Medicines Australia to reveal details of all educational events for which the industry provided hospitality to healthcare professionals. The current edition of the Code[1] extended the disclosure requirements to include public reporting on sponsorship of healthcare professionals to attend or speak at conferences or educational meetings and payments made to healthcare professionals to act on advisory boards or for the provision of consulting services. There is, however, no requirement for the names of individual healthcare professionals to be made public.

Data received by Medicines Australia show that between July 2007 and March 2013, the pharmaceutical industry in Australia spent $321 million on educational events, an average of $57 million per year on 30,000 events for 821,000 attendances. The average expenditure per attendance was $69 with the majority (72%) averaging less than $20.[2]

Transparency Model

In 2012, the ACCC urged Medicines Australia to include the disclosure of payments made to individual healthcare professionals in the next revision of its Code of Conduct.[3] In response, Medicines Australia established a Transparency Working Group to develop a model for enhancing transparency between companies and healthcare professionals. The primary purpose of this measure was,

> *"…to enable health consumers to be better informed about the nature of payments and transfers of value between healthcare professionals and the industry in general, as well as such interactions with industry by their own healthcare professionals."*[4]

A draft of the Transparency Model (TM) [5] was released for consultation as a prelude to the next review of the Code. Under the proposed TM, pharmaceutical companies would be required to report any payments or transfers of value made to healthcare professionals above a certain monetary threshold. Two options were put forward: a fixed $25 threshold or a $10 threshold for recording, with a $100 threshold for reporting cumulative payments to individuals.

Pharmaceutical companies would be required to report the name of the healthcare professional; the amount of the payment or other transfer of value (distributed between the group where appropriate); the date of the payment (singly or 'bundled' where there are multiple payments); and the form of the payment (e.g. cash or in-kind). In addition, they would be required to specify the type of payment or transfer of value, such as consulting fee, honorarium, travel, food and beverage and education. There were a number of proposed exclusions from reporting requirements, most notably payments or transfers of value made under a product research or development agreement (clinical research).

International approaches

The pursuit of greater transparency in the relationship between healthcare professionals and the pharmaceutical industry is rapidly spreading internationally with the enactment of legislation in the USA, France and Slovakia and through the adoption of transparency provisions in industry codes of conduct in a number of other countries including the Netherlands, the United Kingdom, Denmark and Japan.

The recently enacted US Physician Payments Sunshine Act requires that pharmaceutical companies report payments and transfers of value given to physicians where the value is more than US$10. Research is included as one of the categories of payment companies are required to report.

In the Netherlands, under its industry Code of Conduct, disclosure of service and sponsorship relationships agreed between pharmaceutical companies and health care professionals, partnerships of healthcare professionals and the institutions that employ them, is compulsory where the payment, in money or kind, exceeds €500 in any calendar year. This threshold was set in recognition that "the administrative burden would be too great if all such small gifts had to be registered".[6]

The 'ins' and 'outs' of the proposed Transparency Model

As with the US Sunshine Act and the Netherlands Code of Conduct, Medicines Australia's proposed Transparency Model is primarily framed in terms of transparency to the public at large with the purported aim of restoring public trust.

There is, however, considerable variability reported in patients' attitudes to payments and gifts to doctors by the pharmaceutical industry. While some studies report that the majority of patients are "concerned about the effects of interactions between doctors and the pharmaceutical industry"[7], others have found that a majority still approve of drug samples, small gifts and payments for clinical trials.[8] Furthermore, surveys have found that "patients think other physicians are more likely to be biased by gifts from industry than their own physicians".[9]

The idea that the public at large will wish to check up on payments to their own healthcare practitioner is highly questionable.[10] While there is a substantial body of research that demonstrates that prescribing practice can be influenced by gift-giving, many health professionals believe that they are impervious to industry influence[11] and it is highly unlikely that the transparency provisions will alter the behaviour of the vast majority of those healthcare professionals who attend industry sponsored educational events. What is more likely is that it will create an "administrative burden"[6], primarily of small payments which will only serve to hide the larger payments that really need to have the spotlight shone on them.

Although the proposed TM includes the reporting of consulting fees and honoraria, it excludes one of the biggest and most critical elements of the relationship between health professionals and the pharmaceutical industry; payments and other transfers of value for clinical research

associated with the evaluation of pharmaceutical products. There is now irrefutable evidence that industry sponsorship biases published scientific research in favour of the sponsors.[11] [12-14]

The majority of drug research is funded and controlled by the pharmaceutical industry. A Pharmaceutical Industry Council survey[15] in Australia in 2011 found that, in the preceding year, they had conducted 2,107 research studies at a total expenditure of $637 million. 60% of the research had been conducted in public hospitals, 15% in private research institutes and 12% in private hospitals. This dwarfs the money spent annually on educational events.

Putting the 'evidence' back into Evidence-Based Medicine (EBM)

Figure 1 illustrates the author's view of the complex system involved in the development and dissemination of pharmaceutical research findings, the foundation for the evidence base on which training, clinical practice and professional development stand.

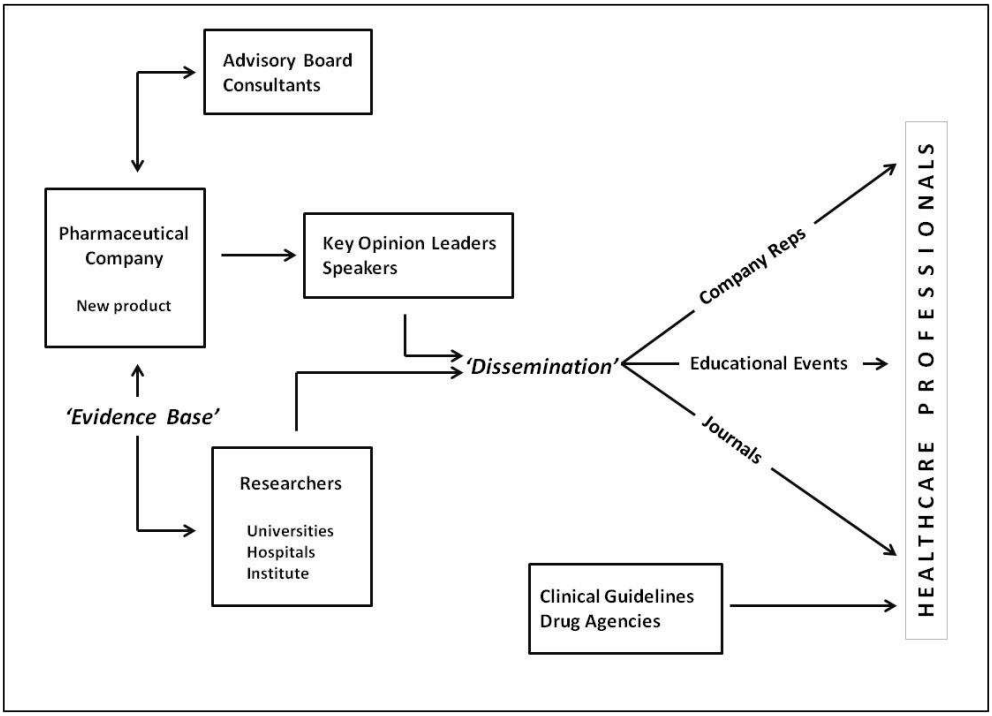

Figure 1. Pathway for the development and dissemination of research findings

Healthcare professionals play a crucial role in researching new products and in the dissemination of research findings to their colleagues. Some of the more influential physicians, sometimes referred to as 'key opinion leaders', may play multiple roles in this system. The public at large, which sits outside this system, is the primary 'lens' through which the various transparency acts and codes have been framed. But will greater public transparency really be able to bring about reform in a system in which the boundaries between the missions of the various players have become so blurred?

Sismondo argues that payments to physicians need to be viewed through a "very different lens".[16]

> *"The larger payments …. to physicians are primarily intended not to affect their prescriptions, but rather to purchase their influence on other physicians' prescriptions; the same is true to payments to researchers. In other words, companies hope to lead medical opinion in their preferred directions through a two step model of influence by hiring and otherwise enrolling some physicians and researchers who will, in turn, influence many others*."

Angell[17] contends that pharmaceutical companies prefer to carry out research with "academic medical centres" primarily to get access to "key opinion leaders". She goes on to add,

> *"These are people who write textbooks and medical-journal papers, issue practice guidelines, …. sit on FDA and other government advisory panels, head professional societies and speak at innumerable meetings and dinners that take place every day to teach clinicians about prescription drugs."*

Fifty six percent of DSM IV members, including all of the members of the panels on mood disorders and schizophrenia and other psychotic disorders, had financial associations with pharmaceutical companies.[18] The leading categories of financial interest held by panel members were research funding (42%), consultancies (22%) and speakers bureau (16%). Similar levels of industry ties were reported for DSM 5 panel members.[19]

A study of the authors of the American Psychiatric Association's Clinical Practice Guidelines for the treatment of schizophrenia, bipolar disorder and major depressive disorder found 90% had financial ties to the pharmaceutical industry.[20]

Brody[21] argues,

> *"It is hard for a conscientious physician today to learn the truth about which drugs work and how safe they are, even if that physician only reads medical journals and does not ever talk with drug sales reps …. since so many of the articles published in reputable journals has distortions introduced by commercial sponsorship."*

Essentially, "marketing goals infuse the creation and distribution of scientific knowledge".[16] Although transparency provisions alone will not be adequate to redress this situation, there would be no more salient place to focus the 'spotlight' than on those parts of the system that are central to the creation and distribution of the evidence base – on payments or other transfers of value to researchers, research institutions and 'key opinion leaders'. These are the areas in which the pharmaceutical industry makes by far the largest investment and it is essential that these activities are included in the provisions of any industry code of conduct.

Increasing the transparency of the system

What public disclosure provisions might do[22], if appropriately targeted is,

> *"…. help physicians with their practices by allowing them to better understand the interplay between the key opinion leaders and manufacturers. …. "Its going to allow*

them to make smarter decisions when it comes to determining who to believe and what type of research to believe."

A study of how physicians interpret research funding disclosures[23] found that disclosure of industry sponsorship negatively influences their perceptions about the rigor and quality of the research methodology and their willingness to believe and act on the findings. Turning the 'spotlight' on the "creation and distribution of scientific knowledge"[16] is likely over time to be one of the most effective strategies in promoting greater openness and methodological rigor in industry supported trials.

Concluding remarks

A more strategic approach to understanding and reshaping the relationship between medicine and the pharmaceutical industry would be to follow the 'trail' of the larger payments that play such a critical role in establishing and promulgating the evidence base for health care. The Dutch have set their threshold at €500 per annum and consideration should be given to setting the threshold in the Australian context at a similar level. Although this would eliminate the bulk of the payments to individual healthcare professionals, shining the spotlight on the larger payments would lead to a better understanding of the interplay between science and marketing. Information on smaller payments could continue to be collected in the current 'aggregate' form.

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