EDITORIAL

Let the sunshine in—making industry payments to New Zealand doctors transparent

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Whilst several countries are enacting legislation to tighten requirements for disclosure of the financial ties between pharmaceutical companies and health practitioners, the situation in New Zealand remains as murky as ever. Due to a lack of transparency in New Zealand it is impossible to know to what extent monetary benefits are flowing from industry to health practitioners in the form of sponsored research, conference sponsorship, consulting fees and other financial incentives.

Although the presence of the government drug-buying agency PHARMAC makes New Zealand's situation unique, the pharmaceutical industry remains active in promoting its commercial interests to health sector personnel. The time is right for a healthy dose of sunlight to shine on these relationships, with the preferred method being legislation similar to the US Sunshine Act which would provide greater transparency for New Zealand health care consumers.

What is the Sunshine Act?

The Sunshine Act was first introduced in the United States in 1976 with the aim of improving transparency in the public sector. Initially the act was focused on the federal government, Congress, federal commissions, and other legally constituted federal bodies and was one of a number of Freedom of Information Acts (http://www.gsa.gov/portal/content/102416).

In 2007 a proposed amendment to the bill that would have included the health care sector was unsuccessful. Subsequently, in 2010 the Physician Payment Sunshine Act (PPSA) was passed as part of the Patient Protection and Affordable Care Act. It covers all manufacturers of drugs, devices, and biological and medical supplies covered by federal health care programs and will require the tracking of all financial relationships with physicians and teaching hospitals. It was signed into law in March 2010 and in September 2014 the information was reported publicly for the first time.1

The extent of the payments was staggering with 4.4 million payments totalling $US3.5 billion. More than half a million doctors and about 1,360 teaching hospitals received at least one payment (and not including continuing medical education payments).2

Why is this legislation considered necessary?

For the past half-century there has been an increasingly close relationship between health care professionals and industries such as pharmaceutical companies and device manufacturers.3,4 Some of these relationships are inevitable as many doctors and researchers are involved in the development of new drugs and other innovations. However, it has also become clear that the relationship has broadened from a strictly advisory one to include promotion and marketing. This is not limited to pharmaceutical products but also includes non-prescription medications such as supplements and sports drinks.5

Whilst doctors and scientists may have advanced the research agenda by identifying gaps in knowledge and assisting in the design of clinical studies for industry, some activities clearly do not fit into that category. Reimbursing doctors for assisting research activities may be reasonable given the widely held view that universities and hospitals should not use education or health money for research. However, it is not uncommon for doctors and researchers to receive payment for membership of...
advisory boards, speaking at industry sponsored symposia, or sponsorship of travel and accommodation to conferences which often incorporate generous hospitality events and may not involve any speaking commitment. Such interactions between doctors and industry could be interpreted as receiving payment or ‘getting something for nothing’.

Increasingly, doctors are being required to disclose associations with industry when presenting at meetings or submitting manuscripts for publication. Although making a declaration of interest has become common at conferences of the major medical societies, many presenters will choose to either mention it briefly, make light of it in a humorous or dismissive way or wear it as a “badge of honour” if they have declarations from a range of companies. However, many of these interactions occur without the requirement for any official disclosure, which means that the extent and value of the interactions are unknown.

A particular area of concern is clinical guidelines, given their key role in supporting clinical decision making and promoting quality improvement in health care and the imperative that they be trustworthy. Conflicts of interest (COI) are an important potential source of bias in guideline development and there is increasing concern that COI, in particular those related to the pharmaceutical industry, may adversely affect the quality of clinical guidelines. Recent cross-sectional studies of guideline group members in North America and Europe have found that financial COIs are common but that there is under-reporting of these by guideline group members. There is evidence that such COI can directly influence the development of clinical guideline recommendations. For these reasons it is now usual for guideline development organisations to request declarations of potential COIs.

Until recently the problem of COI has been addressed by internal regulation at the level of health care practitioners, through ethical obligations, and by codes of conduct for organisations responsible for reviewing new drugs and developing clinical guidelines. Most of these organisations now have detailed policies requiring disclosure and providing guidance about how COI should be handled. Given that such policies are based on trust and rely on self-disclosure there has been no way of auditing the accuracy of the declarations. In addition, these ethical standards and policies while important are, in themselves, insufficient. There is a need for industry to be accountable through external mechanisms such as the Sunshine Act.

**Compliance a major issue**

A national survey in the US reported that 18% of doctors had received reimbursement from industry for costs associated with attending professional meetings and 14% had received payment for consulting, lectures and enrolling patients in clinical trials. Considerable evidence suggests that the relationship between industry and practitioners influences clinical practice and especially drug prescribing. Pharmaceutical company sponsored research is more likely to favour the sponsor’s product than independently funded research. Payments to doctors have been shown to influence their prescribing behaviour. In many instances the recipients of industry benefits are academics or opinion leaders, presumably because of their ability to influence large number of colleagues, students and trainees, and their drive for career advancement.

There have also been concerns that medical students and postgraduate trainees, for whom there may be less scrutiny on interactions with industry, are unduly influenced to prescribe drugs that are promoted by industry. A “PharmFree Scorecard” that grades US medical schools on the presence of a policy regulating interactions between their students and faculty and the pharmaceutical and medical device industries has recently reported that students are more likely to prescribe higher cost and lower value medications if exposed to industry marketing representatives.
Disclosure in the United States

Until the PPSA reported on industry payments to doctors in September 2014, the majority of these payments were under the radar. ProPublica, a group of journalists in the United States mined unstructured data from dozens of websites where payments had been disclosed as a result of lawsuits involving pharmaceutical companies over the years [www.propublica.org](http://www.propublica.org). ProPublica gathered all of these data, which in 2011 covered payments made by pharmaceutical companies responsible for half of all prescription drug sales in the US.

Developed in 2010 as a news application, ProPublica made the database searchable and freely available. The Dollars for Docs news app is updated as new information comes to hand and has been recently expanded, as the Affordable Care Act requires pharmaceutical and medical device companies to publicly report payments they make to doctors and health institutions. As a result of this project, it was possible to report that US$2 billion in payments had been made to doctors and health care institutions since 2009 and 22 doctors were identified who earned at least US$500,000 through such payments, with one doctor being paid over US$1 million. However, as predicted these payments were a significant undercount as the PPSA data have now shown. Without the mandated data being released, we would still be in the dark about the extent of the payments to the doctors.

Even before the PPSA started reporting, the threat of greater transparency had an impact on the level of payments being made to doctors. In December 2013, the pharmaceutical and supplement company GlaxoSmithKline, which according to ProPublica was responsible for US$238.6 million in payments to doctors between 2009 and 2012, said it would stop physician payments. ProPublica reports that the largest US pharmaceutical companies have begun reducing payments to doctors for promotional presentations.

Payments by Eli Lilly declined by 55% between 2011 and 2012, from US$47.9 million to US$21.6 million. Moreover, some of the largest pharmaceutical companies have slashed payments to health professionals for promotional lectures amid heightened public scrutiny of such spending, a new ProPublica analysis shows. Over the same period, payments of speakers’ fees by Pfizer fell 62% from US$22 million to US$8.3 million, while payments by Novartis fell 40% between 2010 and September 2011, from US$24.8 million to US$14.8 million.

International response to the Physician Payment Sunshine Act

After the PPSA was passed into legislation in the United States, Australia and European countries have all either enacted or begun to enact similar legislation.

In 2011 New Zealand and Australian pharmaceutical companies voluntarily adopted a Trans Tasman code of conduct that was part of a global movement initiated by a series of court settlements between government agencies and a group of pharmaceutical agencies. The principles of the code are legitimacy, transparency, independence and appropriateness of the relationship between health care practitioners and companies. However, the code does not include requirement for disclosure of payment to doctors and institutions; for all intents and purposes, there has been no visible change in the practices.

At local conferences, it is still common for companies to host social occasions with generous benefits with little or no educational component. Sponsorship (via payment of airfares, accommodation and registration) to attend international meetings is the norm in some medical specialties.

Medicines Australia, a trade organisation for pharmaceutical companies, has developed a Transparency Model with the purpose of improving transparency about payments between companies and health care professionals. In May 2013 the Transparency Working Group agreed on a set of principles which included collecting and reporting details on all monetary transactions between a
company and individual health care professionals using a single, publicly accessible website. Although the code has recently been revised as outlined above the changes were agreed solely by members of Medicines Australia. However, an “opt out” option for individual health professionals is possible and it fails to implement the concept of a single website for the information.\(^{23}\)

In July 2013 the European Federation of Pharmaceutical Industries and Associations, the body that represents the industry across Europe, announced that its members must disclose details of payments to individual healthcare professionals from 2016.\(^{24}\) Individual countries are yet to finalise how they intend to comply.

In the UK, there is widespread professional support for industry payments to doctors to be made public\(^ {25}\) and the Association of the British Pharmaceutical Industry (ABPI) announced in November 2013 that its member companies have agreed, as part of amendments to its Code of Practice, to disclose payments to individually named healthcare professionals, including consultancy services such as speaking and sponsorship to attend medical education meetings. This will come into effect in 2016.\(^ {26}\) It is unclear, however, if there will be any requirement to force doctors to disclose their payments if they are not willing to consent to this. The onus appears to remain on self-disclosure by professionals in line with UK General Medical Council (GMC) advice.\(^ {27}\)

**What is the current situation in NZ?**

Currently, New Zealand does not have a mechanism for disclosure of payments to doctors from pharmaceutical and device industries. All pharmaceutical companies are required to limit the hospitality provided to doctors by including an educational component but the rate of adherence is unknown and there is no formal oversight or auditing.

An enquiry to Dr Stewart Jessamine of Medsafe, Ministry of Health elicited this reply “The situation in NZ may be different from USA and or Australia as so much of what is available in the public system is purchased via PHARMAC. This double regulatory hurdle of Medsafe’s safety, quality and efficacy, and PHARMAC’s cost-effectiveness may limit the scope for industry to influence prescribing decisions in terms of one brand over another” (personal communication, Dr Stewart Jessamine, July 2014).

However, not all medicines are funded, and not all health care is publicly funded and there are many drugs which continue to be prescribed by clinicians outside of PHARMAC funding. Certainly the industry is still actively promoting new medicines in New Zealand, and so there are concerns about payments to doctors influencing their prescribing. The plans to have a joint Australian and New Zealand Therapeutic Products Agency which would have harmonised the approaches of the TGA and Medsafe have now been abandoned. This transition to a new agency may have provided an opportunity to implement some changes with regard to improved transparency [http://anztpa.org/projects/harmonisation.htm](http://anztpa.org/projects/harmonisation.htm).

**What could district health boards, medical societies and universities do to assist?**

District health boards, medical associations and societies and universities all have a role to play in improving transparency about the interactions between doctors and industry. For example, DHBs provide funding (as part of the national multi-employer contract agreement (MECA) for senior medical officers) via a CME fund entitlement to reimburse senior doctors for expenses incurred by attending conferences and courses.

Greater scrutiny of the appropriateness of conference leave and the relevance, quality and independence of specific meetings could be introduced. This is largely left to clinical leaders to
“police” with a natural disincentive to deny leave to colleagues they work with. DHBs could request that all DHB SMOs disclose their COIs in order to receive their CME funds.

Academics in the United States have called for specialist medical societies to disengage from industry, not allow conflicted members on guidelines groups, and avoid COIs within senior positions in the organization. Some New Zealand colleges have followed this example; notably both the Royal New Zealand College of General Practitioners and the Royal Australian and New Zealand College of Psychiatrists no longer have industry sponsors and limit the impact of industry at their conferences. Academic institutions could also assist by making available COI statements and details of payments for their staff.

Industry research is often considered a good way to advance an academic career, as it may lead to international presentations and publications and prominence in the field. In the United States, most medical faculties require disclosure and have policies for monitoring these.

Conclusions

In the final analysis it is a matter of trust. How do we know if the information and treatments we are receiving from doctors and other health professionals have not been influenced by payments or sponsorship from certain related companies? Certainly the results of research from pharmaceutical sponsored studies have found such studies to be biased and favouring the companies’ products.

To date the focus has been on professional self-regulation but evidence from clinical guidelines suggests that it is insufficient to wholly rely on clinician self-disclosure with an expectation that clinicians will always act in accordance with their regulatory body’s code of practice. There is a need for tighter external regulation of industry as achieved through the US Sunshine Act. Whilst there is some concern that disclosure per se is insufficient to substantially improve matters, the impressive reduction in payments that is already happening in the United States provides evidence that change by industry is possible and will make a difference.

New Zealanders should be rightfully proud of our public health system and our access to a range of drugs and procedures at competitive prices. However, we can’t afford to ignore the fact that many commercial groups seek and establish relationships with health professionals that may undermine health policy development. There is an urgent need to have this information made transparent so that our clinicians and policy-makers are seen as making independent trustworthy decisions on health care.

We consider that New Zealand should adopt international best practice with respect to transparency over industry payments to individuals. Shining some light on the relationships is likely to be good for our health.

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