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23 April 2013

Senator Helen Polley
Chair
Senate Standing Committee on Finance and Public Administration
PO Box 6100
Parliament House
Canberra ACT 2006

Submitted online.

Dear Senator Polley

Therapeutic Goods Amendment (Pharmaceutical Transparency) Bill 2013 (Cth)

The University of Sydney supports the broad intent behind the Bill: safeguarding the integrity of prescribing medicines in Australia by ensuring that pharmaceutical companies cannot exercise undue influence over the prescribing behaviour of medical practitioners.

We welcome Senator Di Natale's initiative in preparing this private senators' bill. The issues the Bill seeks to address are important to long term integrity and sustainability of the Pharmaceutical Benefits Scheme and the Australian health care system. We trust that the Bill will stimulate valuable discussion in the Parliament, within and between relevant professions and industries, and in the community more broadly, about the appropriate nature of the relationship between pharmaceutical companies and health professionals with the power to prescribe, and about how best to regulate these interactions in all their various forms.

As a research-intensive university with a particular focus on health and medical research, the University of Sydney is concerned, however, that if passed into law in its current form, the Bill may have unintended consequences for the conduct of public good research in Australia. The scale, quality and relevance of Australia's health and medical research all rely on continual engagement and collaboration between universities, medical research institutes, clinicians throughout the health system, and industry partners of various kinds. We are concerned that the Bill as currently proposed may inadvertently do damage to these largely symbiotic relationships, and ultimately to patient health outcomes in terms of access to the more effective treatments that result from Australian research.

We are concerned, for example, that the Bill as drafted:

- may adversely impact on legitimate health and medical research, dissemination of public sector research, and training and continuing professional development conducted in Australian universities;
- will be impractical to implement, costly to police, and may impose a high regulatory burden upon Australian universities and other publicly funded research organisation;
- may unintentionally put universities at risk of significant penalties;

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- is too stringent – stronger than the standards of Medicine Australia's self-regulatory code of conduct, and stronger than those of the recently enacted US Physician Payment Sunshine Act – and its definitions and details require more work; and
- is premature given the current review of Medicine Australia's code of conduct.

Impact on legitimate activities in partnership with pharmaceutical companies

We are concerned that the Bill will unintentionally diminish industry's capacity and willingness to collaborate with Australian universities, and to sponsor legitimate university-led education and research initiatives. Ultimately this would affect the capacity of universities to disseminate the findings of their researchers and to provide training to health professionals. Here are two examples:

- Research symposia and educational events driven by the University and hosted in Australia can receive untied grants and sponsorship from industry. The Bill introduces a substantial regulatory compliance burden associated with that sponsorship for both the sponsor and organiser. The $100/day limit is also barely sufficient to cover basic catering costs at an average city-based venue.
- A government-funded grant with a substantial industry contribution, such as the ARC linkage mechanism, might require a workshop to be held at an international location. The proposed compliance requirements might make it impossible for the industry partner, or its ARC-approved funding contribution, to be involved.

Is additional regulation necessary?

The University is a large and complex organisation experienced in dealing with industry. It has a mature suite of policies and procedures to identify and manage activities giving rise to opportunities for, or perceptions of, undue influence and conflict of interest. See for example, the following policies available through our policy register (http://sydney.edu.au/policies/):

- *Code of conduct for staff and affiliates*
- *External Interests policy*
- *Research principles*
- *Research agreements policy*
- *Code of conduct for responsible research practice and guidelines for dealing with allegations of research misconduct*
- *Gift acceptance and administration policies*
- *Reporting wrongdoing policy*.

Most Australian universities would have similar mechanisms in place, and they provide ample opportunity to verify the appropriateness of relationships between our staff and industry, and to manage potential conflicts of interest. We note that the Medicine Australia's Transparency Working Group is currently reviewing its 2012 Code of Conduct to better address transparency and is likely to recommend increased scrutiny of relations between the industry and healthcare practitioners. The University's integrity mechanisms will be reviewed in the light of any changes to that Code. We therefore recommend postponing the Parliament's consideration of the Bill until the outcomes of that review are available for public consultation.

We are concerned by the potential increased regulatory burden for universities, government agencies such as the Therapeutic Goods Administration, and for hospitals. We ask whether a regulatory impact assessment been carried out for this Bill, in order to inform Parliament's consideration of the desirability of the proposed approach.

THE UNIVERSITY OF SYDNEY

Issues with definitions

The Bill as drafted is not aligned with the current relationship between medical registration and authority to prescribe. Not all "registered medical practitioners" have that authority; and not all prescribers are "registered medical practitioners" – for example, dentists also prescribe.

Similarly the definition of "regulated corporation" may unintentionally capture universities that import regulated pharmaceuticals for medical research or to conduct clinical trials on behalf of international pharmaceutical companies, exposing them to the penalties and regulatory requirements intended for that industry.

If the Bill is not intended to apply, or apply in the same way, to universities, their staff and affiliates, then we recommend that consideration can be given to exempting these organisations and individuals, or to otherwise mitigating the impact that the Bill would have on these components of the health sector.

If it would assist the Committee with its consideration of the Bill, we would be pleased to answer any further questions it may have, or to provide appropriate representatives to appear before the committee.

Yours sincerely

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