DISSENTING REPORT BY COALITION SENATORS

Introduction

Coalition Senators do not support the conclusion of the majority report that the draft regulations "satisfactorily address the issues that were raised during the Committee's earlier inquiry into the National Health Amendment (Pharmaceutical and other Benefits – Cost Recovery) Bill 2008" because clearly that contention is not supported by the weight of evidence presented to the committee.

Clearly there remains significant opposition to the proposal to move to cost recovery, and the concerns surrounding that proposal have not been mitigated by the release of the draft regulations.

This was best articulated by Professor Carney, Chair of the Therapeutics Advisory Committee, Royal Australasian College of Physicians

> **Prof. Carney**—I would first like to thank you for allowing the college and myself to comment on this PBAC funding cost recovery model again. The last time, when I was in Canberra and commented on this, I mainly tried to raise various issues and did not really come up with a decision as to what the college and its affiliated speciality societies felt about the proposal. Since then, I have had a chance to talk not only within the college, including my therapeutics committee, which met two days ago, but also to a number of affiliated specialty societies—not all, but a fair number including oncology, rheumatology, paediatrics, geriatrics, nephrology, cardiology and a couple of others. We have a large number of the various specialty groups, specialist physicians around the country who are associated with the college. Following those discussions, ***I can say with some confidence that there is no support for the proposal before the Senate at the moment.*** (emphasis added)

and

> **CHAIR**—My understanding is that you still have concerns, the ones you had when you originally gave evidence. You do not, at this stage, feel as though you have had them addressed?
>
> **Prof. Carney**—No, I have not. I see the system as unchanged and with the potential for getting worse. I can understand the government's problems in the Senate at the moment; we all read about that in the paper—probably a bit too much! But I wonder whether the amount of money the government will get from it is really going to be worth it in the long term.

Coalition Senators note that it has not been practice to release draft regulations prior to the passage of legislation and appreciate that the committee has had the opportunity to provide this scrutiny on behalf of the Senate. We are concerned however that the draft regulations were not released until after the committee had reported.

We also concur with the majority report that considerable time and effort would have been saved by the committee and the Senate had the draft regulations been available during the earlier inquiry into the Bill.

Consultation

There remains a considerable difference of opinion between the Department of Health and Ageing (DoHA) and industry over the definition and quality of consultation on the draft regulations.

We reiterate our view that it is unreasonable to assert that there was a seamless process of consultation between the two governments pre- and post the 2007 election.

We further express concern that the perception that forwarding the draft regulations to certain members of industry with an invitation to respond with any issues is genuine consultation, particularly given that the consultation process had been questioned in the previous inquiry.

This is born out by the fact that only two of those circulated (12) responded to the information circulated.

Medicines Australia stated the following in relation to previous experience of consultation with the Department

> **Senator COLBECK**—So, from your experience of consultation with the department, you would have difficulty in calling this 'consultation'?
>
> **Mr Delaat**—Absolutely. We would have great difficulty in defining this as consultation.

A similar response was received from the Australian Medical Association with the added perspective that the interaction of the measure with the Senate process had influenced expectations to consultation.

> **Senator COLBECK**—Basically, I think we are on the same track. Can I go back to your interactions with the department since the last hearings and in particular since the report came out? What communications has there been between the AMA and the department in respect of the issue of initially the draft regs and then the second incarnation that had the explanatory notes attached?
>
> **Mr Sullivan**—We received those from the department by way of its normal dissemination of information. I have not had direct dealings with the department. We have not had any interaction with the department in the interim.
>
> **Senator COLBECK**—Were there any specific requests that came with the documentation? You were basically just provided with that as part of an information process?
>
> **Mr Sullivan**—It is my understanding that it is the latter: the dissemination of information from the department.
>
> **Senator COLBECK**—So it could not be called a consultation process.
>
> **Mr Sullivan**—We have not been consulted per se. Like many groups we have been watching the political debate in the Senate and we responded accordingly to this process. Therefore our understanding of how things will work is the same as everybody else's.

> **Senator COLBECK**—So your response has effectively been to this committee process rather than necessarily the department or the government at this particular time?
>
> **Mr Sullivan**—That is correct.

These responses reinforce previous concerns expressed by Coalition Senators regarding consultation on this measure.

Operation of Regulations

It was obvious from evidence that the provision of the draft regulations has given industry and those interacting with the Pharmaceutical Benefits Scheme a much better understanding of the operations of the measure than briefings provided by the department, and that the process had prompted some amendments.

It is clear however that the release of the regulations had not allayed concerns regarding the concept of cost recovery for the PBS.

> **Mr Sullivan**—…the AMA would like to reiterate its concern about the government policy to introduce cost recovery for the Pharmaceutical Benefits Advisory Committee process. There is no net benefit to the Australian people in requiring pharmaceutical companies to pay application fees for PBS listing processes. These companies will simply factor this cost into their listing prices and claim them as legitimate business expenses for tax purposes. The potential consequence for the Australian people is that companies will decide there is no business case to bring a low-volume, low-priced product to the Australian market. These will be medications for small populations, medications for palliative care, oncology and our Indigenous Australians, for example.

and

> **Senator COLBECK**—You say that the draft regs do not adequately address your concerns. Fundamentally, can that be changed or do you have a basic view that cost recovery is not the process to be undertaken with respect to this particular measure?
>
> **Mr Sullivan**—Yes. In the spirit of the AMA's engagement we are trying to make something we think is not so good maybe slightly better. As we said in our first submission and I tried to reiterate, we do not believe cost recovery should apply in this field.

The Department had also indicated that the regulations were framed and would operate in a similar manner to those of the Therapeutic Goods Administration (TGA), the terms and procedures of which industry is quite familiar.

The proposed similarity between the two processes however was an additional point of concern with those at the coal face dealing directly with patients

> **Senator COLBECK**—I understand what you are saying but given that a lot of the precedents and process that is proposed for the PBAC process is lifted from the TGA process that would I presume reinforce your concerns?
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> **Prof. Carney**—Yes. It would be just be PBAC running the way TGA does. That is my big concern because we are finding it extremely difficult. As I said certain groups now put it on their websites. You will find if you go to the MOG website, which is one of the groups, you will see medications. If you look at the indications approved by TGA, and you look at theirs, they are quite different. Because they have decided

that for their members and their patients they will put it down as they see it. There are legal issues in this of course. I do not quite know how they are going to be resolved. It is an area of confusion but again I would not want to see PBAC end up being in a situation where they are tied by having to get the money and then having to rely on industry who are going to say, 'What's in it for us?'

Conclusion

Coalition Senators reaffirm their view that cost recovery not be pursued, with that view supported by the overwhelming weight of evidence at both inquiries conducted into this measure.

Senator Gary Humphries

Senator Judith Adams

Senator Sue Boyce

Senator Richard Colbeck

Senator Scott Ryan