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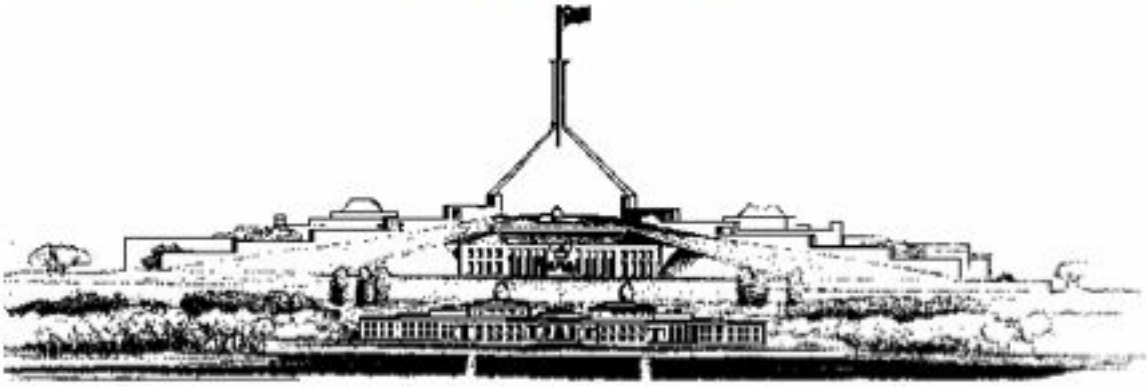

HOUSE OF REPRESENTATIVES

PROOF

HEALTH AND AGEING LEGISLATION AMENDMENT BILL 2003

Second Reading

SPEECH

Thursday, 4 March 2004

BY AUTHORITY OF THE HOUSE OF REPRESENTATIVES

SPEECH

Date	Thursday, 4 March 2004	**Source**	House
Page	26002	**Proof**	Yes
Questioner		**Responder**	
Speaker	Gillard, Julia, MP	**Question No.**	

Ms GILLARD (Lalor) (12.45 pm)—The Health and Ageing Legislation Amendment Bill 2003 deals with a number of amendments to various acts within the health and ageing portfolio, along with a consequential amendment to the Veterans' Entitlements Act. The bill deals with a number of issues, and I will take the House through them briefly.

The bill deals with a simplified claiming process. Where a medical service is provided as part of a medical purchaser-provider agreement with a private health insurance fund, the National Health Act 1953 requires the medical service provider to forward all accounts to the fund. If this provision is not complied with, the health fund is prevented from paying benefits in excess of 25 per cent of the MBS fee. This creates an anomaly between the medical purchaser-provider agreement arrangements and other gap cover arrangements, to the detriment of consumers. The health fund is prohibited from extending coverage to any gap that may exist, and the member is left with an unexpected out-of-pocket expense. This bill removes this anomaly.

The bill makes a number of provisions to correct unintended consequences of earlier legislation. The Health Insurance Act 1973 is amended to restore specialist recognition status for the purpose of ensuring access to Medicare benefits at the specialist rebate level. This status was unintentionally removed. Previous legislation had also unintentionally allowed all overseas trained doctors to receive Medicare benefits for assistance at operations in areas that are not districts of work force shortage. This amendment clarifies the intent of government policy regarding maldistribution in the Australian medical work force and the resulting difficulties experienced by some rural communities in accessing general practitioner services. Finally, in terms of the minor parts of the bill, a number of typographical errors, punctuation errors and incorrect cross-references are corrected, with other minor consequential changes.

But, as the Parliamentary Secretary to the Minister for Health and Ageing indicated, the bill also deals with the membership of the Pharmaceutical Benefits Advisory Committee and increases the membership by four persons, from 11 to 15. This measure is being undertaken in order to cope more effectively with the increasing workload of the committee. The PBAC is at the centre of our Pharmaceutical Benefits Scheme, which has been the envy of the world in that it has delivered medicines to Australian citizens at world's best prices and enabled those medicines to be affordable for Australians. If we look around the rest of the world—and I think many Australians know this from watching television, from having friends who live overseas or from having travelled overseas themselves and having had to deal with a health condition when they were over there—we see that our access to affordable medicines fundamentally relies on the Pharmaceutical Benefits Scheme. That scheme delivers medicines to Australian consumers at incredibly cheap prices by world standards. The PBS is the successor of a scheme put in place by the Chifley government—another Labor initiative in the health area.

The PBAC, which is at the heart of this process, has its membership expanded by this bill. The composition of the PBAC has been a political issue for some time. Generally, we on this side of the House believe that the PBAC does a great job under difficult circumstances. But it should be noted that during the last term of the Howard government there were serious concerns that the then Minister for Health and Aged Care, Minister Wooldridge, was manipulating appointments to the PBAC in a way that would undermine the independence of the committee and diminish consumer representation in the process. Fortunately, none of those kinds of concerns are raised by this bill, which deals simply with the expansion of membership.

The bill also makes a number of other minor amendments in relation to the PBS. It clarifies the scope of section 100 of the National Health Act 1953, which provides a mechanism for special distribution arrangements for highly specialised medicines where normal PBS distribution arrangements are inappropriate. Medicines currently available under section 100 include immunosuppressive agents which prevent transplant rejection, drugs used to counter the side effects of chemotherapy, anti-HIV-AIDS drugs, drugs for the treatment of hepatitis and others.

The bill makes better arrangements for the reimbursement of pharmacists in circumstances where a pharmacist has relocated without applying for approval and cannot lawfully be paid for any pharmaceutical benefits supplied

from as yet unapproved premises. It will allow an agent to make and sign an application for a PBS safety net concession or entitlement card, or for an additional or replacement card, on behalf of a person who is qualified for a card but is unable to sign the application in person. It provides for consistency between pharmacy and hospital supply in the determination of forms, strengths, brands, maximum quantities and repeats of PBS medicines. It also clarifies the provisions for cancelling an approval to supply pharmaceutical benefits.

Given the nature of these changes, the attitude of the Labor Party to this bill is that this is a series of necessary and generally technical amendments, and it is our intention to support the bill. However, today of all days, dealing with the bill in this House has the sense about it of fiddling while Rome burns. I am referring to the as yet unknown but highly contentious changes that the US free trade agreement appears to be making to the Pharmaceutical Benefits Scheme.

Before I deal with some of those changes—the matters on which I am about to address the House are comprehended in a second reading amendment which I will move at the conclusion of this contribution—I point out that, in the course of the negotiations with the United States about the free trade agreement, time after time Howard government ministers, whilst using on many occasions what we thought were weasel words, assured Australians that the US free trade agreement would not in any way undermine the functioning of the Pharmaceutical Benefits Scheme. We on this side of the House were always deeply suspicious. You do not need to be a trade negotiator to know that one of the things most sought by the United States out of the free trade agreement arrangements was better access, from its point of view, to the Australian market for its drug companies. We are all aware that many of the leading drug companies of the world are US based. So you do not need to be a trade negotiator to know that one of the biggest things on the table from the point of view of the United States was better access for its drug companies to the Australian market.

Mr Cox—I think the problems were overridden by people who were not trade negotiators.

Ms GILLARD—My colleague the member for Kingston reminds me that perhaps where all of this went off the rails was that the real trade negotiators in the piece were overridden by people acting on other agendas. We will probably get to the bottom of that over the coming few days. My point is that we always knew that there would be pressure from the United States side to make changes to the Pharmaceutical Benefits Scheme. We always knew that those changes would have two motivations.

Of course US drug companies are interested in the Australian market and in selling their products here at the best possible price. That is an understandable objective for an organisation that, by its very nature, is seeking to maximise profit. There was pressure from the United States drug companies about the free trade agreement and its implications for the PBS, but we were also aware that these companies had a bigger agenda. One of the things that most disturbs them about the Australian Pharmaceutical Benefits Scheme is its demonstration effect. The PBS demonstrates that a national government can manage a supply scheme of medicines to its citizens and keep prices down. Other nations around the world are known to ask American drug companies why drugs cannot be supplied to their citizens at the same price those drugs are being made available in Australia—hence the issue of demonstration effect.

The agenda for the US drug companies was bigger than the capacity to do more in the Australian market. It was also the question of the demonstration effect and how that skews, or has the potential to skew, prices for them in other markets. We were always deeply suspicious that the nature of the assurances—when you get assurances from this government you are necessarily suspicious—given by the Howard government were not good enough. We were always deeply concerned about matters associated with the PBS which would be detrimental to its functioning and, at the end of the day, would impact on price for Australian takers of medicines or on the amount Australian taxpayers pay to subsidise the PBS. Changes to the scheme would mean that, one way or another, Australian consumers of drugs or Australian taxpayers, who support the PBS, would lose out.

I had a very brief opportunity this morning to look at the free trade agreement. As you would be aware, Madam Deputy Speaker Gambaro, after a few days of inexplicable delay, the FTA has been made available and bits of it can be downloaded. The FTA is a very lengthy and complex document. When you go to the sections which deal with pharmaceuticals, what started off as a very deep suspicion seems to be more and more factually based. Given the time frame in which these documents became available to us—they became available only this morning, after a media statement by the Minister for Trade—I am not in a position to offer to the House a complete analysis of what has gone on here.

From my examination of the documents, I have a series of questions that I think it is incumbent on the Howard government—the Prime Minister, the trade minister or the health minister—to answer. My challenge to them is to answer these questions and, if they are able to do so, reassure Australians who rely on the PBS in times of illness that the impact of this trade agreement on the PBS will not end up lumped onto Australian consumers or taxpayers as increased costs.

The first of the issues I raise in that regard comes out of the annex which deals with pharmaceuticals. As I have indicated, this is a complex document with a number of annexures, one of which deals with pharmaceuticals. The annexure has agreed principles. The parties to the agreement have put down their agreed principles in the area. The parties say that there is an important role played by innovative pharmaceutical products in delivering high quality health care. They go on to talk about the importance of research and development in the pharmaceutical industry and about appropriate government support, through intellectual property protection and other policies; deal with the need to provide timely and affordable access to innovative pharmaceuticals through transparent, expeditious and accountable procedures; and recognise the value of innovative pharmaceuticals through the operation of competitive markets or by adopting or maintaining procedures which appropriately value the objectively demonstrated therapeutic significance of a pharmaceutical.

On the surface, you might ask what is wrong with that. What is wrong with it is that of course our processes —starting off as they do with the Therapeutic Goods Administration and then going through the PBS stages, including the work of the Pharmaceutical Benefits Advisory Committee—are assessing whether or not drugs are safe or clinically effective for the purposes for which they are said to be effective. There are two thresholds there. The first is: is it safe? Is it going to do you harm if you take it? The second threshold is: is it going to do you some good? Is it clinically effective in dealing with the condition that the drug companies say it has been designed to combat?

The third and essential arm of the Pharmaceutical Benefits Scheme, which is not anywhere in these agreed principles, concerns the question of cost effectiveness. It is most imperative to assess the question of cost effectiveness when one is dealing with innovative pharmaceuticals, because drug companies necessarily, all the time, come up with new products dealing with conditions that are currently dealt with by older drugs. In our PBS system we say that it is fine and good if there is an innovative product, but we ask whether it is cost effective compared with the older drug and whether the older drug—which is necessarily cheaper and often generic—does the same work. If the older drug does the same work then we do not just purchase the new one for the sake of being seen to purchase an innovative pharmaceutical; we ask what the health outcome is that we are looking for here and we go down the track of asking how we can get that health outcome with cost effectiveness. I am deeply concerned that in failing to deal with the issue of cost effectiveness up front in the agreed principles there has been a shift on that emphasis in our PBS. If that were to shift it could only mean one thing, and that would be more expensive medicines or more taxpayers' money supporting the PBS.

Then there is the heading of `Transparency', which is ironic. We are well used to ironic headings for documents in this place, having seen the Workplace Relations Legislation Amendment (More Jobs, Better Pay) Bill 1999, the so-called A Fairer Medicare package and all the rest. In what is another ironic heading in a series being used by the Howard government, under the heading of `Transparency' we have a series of guidelines about the process in which drug companies engage to get their product on the Pharmaceutical Benefits Scheme. At the end of that, it says:

(f) make available an independent review process that may be invoked at the request of an applicant directly affected by a recommendation or determination.

What is being suggested here is that, if the Pharmaceutical Benefits Advisory Committee—the expert committee—have said, `We do not think your drug is worthy of a listing on the PBS,' there is going to be some independent review process beyond that so that a drug company whose drug has been knocked off will be able to have a further review.

I have said that that is under the ironic heading of `Transparency', but the irony comes from the fact that the Minister for Health and Ageing, Minister Abbott, is refusing to rule out this process happening in secret behind closed doors. So under the heading of `Transparency' we are going to have a way for drug companies to appeal against the current expert committee that runs the PBS, and in the name of transparency that process could well occur behind closed doors—and the Australian consumers of medicine and the Australian taxpayers who end up paying the price for medicine will have no idea what happens behind those closed doors.

Presumably, what will happen is that a drug that has been knocked off by the expert Pharmaceutical Benefits Advisory Committee could go into this black-box arrangement behind closed doors in a secret room and a new decision could come out the other side: `Yes, it is going to go on the PBS.' There will be an extra cost for Australian taxpayers and an extra cost for people who buy medicines. None of this money is ever the Howard government's money—the Howard government is not the owner of any money; it is only the custodian of Australian taxpayers' money. Australian taxpayers' money could end up being spent on drugs, with money going to American drug companies, and we the taxpayers would have no idea what happened behind those closed doors. If Minister Abbott has a truly transparent process in mind then you would think it would be a pretty simple thing to say at a media conference, `I absolutely rule out any suggestion that this process is going to happen behind closed doors.' He has certainly done the complete opposite of ruling it out. That is a question that needs to be dealt with by the Howard government.

The documents do not actually answer the sixty-four dollar question, which is not just about where this process is going to happen—whether this is going to happen openly or secretly—but about what the process consists of. All we are told is that it is going to be an independent review process. We are not told by whom it is to be conducted, who gets to go there, what they will say, what the standard of proof is or whether cost effectiveness is going to be an issue. All of those things are left unsaid.

There are only three logical possibilities, I suppose, as to why they are left unsaid. It could be that the Howard government has agreed to them and does not want us to know what they are—that is logical possibility No.1. Logical possibility No.2 is that the Howard government has not agreed to them and has no idea what they are. If the Howard government has not agreed to them and has no idea what they are then, given the significance of this process to the functioning of our Pharmaceutical Benefits Scheme, you would have to say that what we have today is not enough to tell us what the FTA has done to the PBS.

A subsequent question arises: if they have no idea what these processes are, then who is going to work it out? In all of this documentation, the only likely suspect is the newly established Medicines Working Group. Once again, this is Orwellian talk here—you can tell that people connected with the Howard government had a hand in drafting this. The objective of the Medicines Working Group, which is going to comprise American and Australian officials, shall be:

> ... to promote discussion and mutual understanding of issues relating to this Annex ...

I do not know how much more vaguely you could draft it than that. Presumably, after they have talked about the philosophical questions of good and evil and war and peace, then they will start promoting `discussion and mutual understanding of issues relating to this annex'. It is just a drafting absurdity. But, in all of this documentation, this group is the only logical starter for working out how this review process is going to work if the review process is not currently agreed.

My challenge to the Howard government is this: have you agreed upon a review process, and, if you have, what is it? It is our PBS, not your PBS; it is our taxpayers' dollars, not your taxpayers' dollars. We have a right to know. And, if you have not agreed upon the process, then who is going to agree upon it? Will it be this group and, if so, who is going to be in this group, because we do not know that? In what time frame is that agreement going to be made? Are the people who take medicines, who pay for medicines and who are the taxpayers—the people who fund all of this—going to get a say in how all of that is set up? All of those questions are unanswered at the moment and are fundamental to the functioning of our PBS.

Thirdly, this annex deals with the question of the direct dissemination of what is called health information about the functioning of pharmaceuticals to consumers over the Internet. We are concerned, and remain concerned, that this is the thin end of the wedge approach to reaching the situation that prevails in the United States where drug companies directly market pharmaceuticals to consumers—where you can turn on your TV and see an ad for a drug. We know that leads to people watching the TV and thinking, `I think that is what's wrong with me,' and, `I think I might be a bit better if I take that drug.' They go to the doctor and they say, `I want that prescribed to me.' So it distorts prescribing practices—and it is meant to distort prescribing practices. People only advertise products if they want you to buy them. Toyota does not put ads on TV just for the fun of it; it puts ads on TV because it quite likes people to buy Toyotas. If drug companies were putting ads on TV, they would not be doing it just for the fun of it; they would be doing it because they would quite like people to buy their drugs. Is that where we are going? Is the Internet the starting point to direct-to-consumer marketing of pharmaceuticals? This can have highly negative health consequences, with people effectively self-diagnosing, and certainly highly

negative cost consequences, because people go to their doctors and demand and get drugs they do not need. That is a very big issue.

Then, as you work your way through the morass of this package, you get to an associated exchange of letters. There were many letters exchanged back and forth in cementing this free trade agreement, but one exchange of letters is on the PBS. It deals again with this independent review process about which I have spoken. Disturbingly, in section 4 in this exchange of letters between our Minister for Trade and Mr Robert Zoellick, the United States Trade Representative, it says:

> Australia shall provide opportunities to apply for an adjustment to a reimbursement amount.

I do not know what sort of language you needed to study at school to be able to decipher that, but it clearly was not one that was taught to me. The only meaning one can suggest for it is that there is some question of reimbursement funding being available flowing from Australia to America—or to Americans or American companies—arising out of the arrangements that have been struck around the PBS. What is that about? That will be taxpayers' dollars, so we have a right to know. I ask the Minister for Trade—or, in the likely event that he cannot explain it, the Minister for Health and Ageing—to come into the House and explain to us what that means.

There is another letter annexed to the free trade agreement about which I am very concerned. This goes to the question of blood products. As people would probably be aware, CSL deals with blood fractionation in Australia, and we have a national health policy that we only use Australian blood. So people donate blood, the necessary processes are undertaken in relation to that blood and people receive blood—and it is all Australian blood. This document commits Australia to reviewing its arrangements for the supply of blood fractionation services, and that review needs to be concluded no later than 1 January 2007—so we are already committed to a review. It has the Commonwealth committed to recommending to the Australian states and territories that future arrangements for the supply of such services be done through tender processes—so we are talking about tendering arrangements. But what deeply concerns me about this section of the document is that it says what appears to me to be two quite contradictory things. It says:

> A Party may require that blood plasma products for use in its territory be derived from blood plasma collected in the territory of that Party ...

That would seem, on the surface, to imply that Australia could insist that we use only blood plasma products generated from Australian blood. But it then goes on to say:

> Australia confirms that it will not apply any requirement for an applicant for approval of the marketing and distribution of a U.S. blood plasma product to demonstrate significant clinical advantage over Australian-produced products.

So it is clearly contemplating a supply arrangement relating to blood where we would not be able to refuse the US product on the basis that we were claiming that there was a significant clinical advantage. Once again, we have only had these documents very briefly.

My question, and it is a very serious one, to the Howard government is: what does that mean for the longstanding policy that Australia be self-sufficient for blood products—that Australians receive blood products derived and produced from Australian blood? To me, that seems to be a fundamental question that the Howard government needs to answer. Clearly, the questions are of such significance that they need to be dealt with and ought to be dealt with in the context of this debate today. To ensure that that can occur, I now move the second reading amendment standing in my name:

That all words after “That” be omitted with a view to substituting the following words:

“whilst not declining to give the bill a second reading, the House condemns the govern-ment for:

(1) planning to cover up bulk billing figures by electorate until after the next election;

(2) causing a bulk billing crisis;

(3) trying to divert attention from its plans to destroy Medicare by introducing so-called `safety net' arrangements which will make 98% of Australians worse off and which will waste $72 million of precious health dollars on administration; and

(4) consistently ignoring the advice of the Pharmaceutical Benefits Advisory Comm-ittee thus depriving many sick Australians of affordable access to cost-effective medic-ations while agreeing to a Free Trade Agree-ment with the USA which:

(a) has the potential to undermine the Pharmaceutical Benefits Scheme over time through the establish-ment of an on going Australia/USA Medicines Working Group;

(b) has ensured US Pharmaceutical comp-anies can challenge the decisions of the expert committees that advise govern-ment on PBS listing and price;

(c) may force changes to the current Austra-lian blood plasma fractionation arrange-ments with conseq-uences for the safety of blood products; and

(d) may result in job losses in Australian firms which manufacture generic medic-ines as a result of changes to patents and intellectual property protection".

The DEPUTY SPEAKER (Ms Gambaro)—Is the amendment seconded?

Mr Stephen Smith—I second the amendment.