

Submission to the Senate Select Committee on the Free Trade Agreement between Australia and the United States of America

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Introduction

The Australia Institute conducted a number of research projects into the likely impact of the Australia – US FTA on Australia with a particular emphasis on the likely impact of the changes sought by US pharmaceutical companies on the cost of medicine in Australia. The reports published by the Institute include:

- Trading in Our Health System? The impact of the Australia-US Free Trade Agreement on the Pharmaceutical Benefits Scheme, Australia Institute Discussion Paper No. 55, Dr K. Lokuge and Richard Denniss (May 2003)
- A backdoor to higher medicine prices? Intellectual property and the Australia-US Free Trade Agreement, B Lokuge, T Faunce and R Denniss (December 2003).
- Comparing Drug Prices in Australia and the USA: The implications of the US-Australia Free Trade Agreement, (July 2003).

These reports are attached to this submission.

Overview of the negotiation process.

While the Commonwealth Government held a large number of briefings and consultations prior to the end of the FTA negotiation process the Government was in no way forthcoming about the nature of the FTA negotiations. In fact, at times representatives of the Australian Government, including Trade Minister Mark Vaile, misled both the Australian public and the Australian Parliament.

‘The member for Rankin and many other members opposite should note what has been stated on a number of occasions by the United States chief negotiator, Ralph Ives. He has said, ‘We are in no way going after the PBS.’ Now the Labor Party still cannot get the message . They cannot understand simple English: They are not going after the PBS.’ (Hansard, Monday, 26 May, 2003, House of Representatives, p. 14869).

As has since been confirmed by Australia’s chief negotiator, Stephen Deady, the Australian negotiators were under significant, and continuous pressure from US

negotiators to make significant changes to the PBS from the start of the negotiations (March 8, 2004, Department of Health and Ageing FTA briefing).

The Government continues to maintain that the PBS was not 'on the table' by claiming that no formal position was ever put by the US. The fact is that changes to the PBS were an integral element of the negotiation process from the beginning of the FTA negotiations. The Commonwealth Government misled the Australian public when it attempted to reassure them that the PBS would not be part of the FTA negotiations.

Impact of the Australia-US FTA on the PBS

The Australia-US FTA will result in a higher cost to the Commonwealth Government of providing the existing quantity of medicines through the PBS. While prices will not raise by as much as the US drug companies would have liked, the changes are likely to result in both higher prices in the short term and a faster rate of growth for drug prices in the medium to long term.

The FTA will result in higher medicine prices for a number of reasons. First, the development of a 'review process' will place upward pressure on prices. The details of the appeals process are yet to be finalised as they are not actually specified in the text of the FTA or the side letters. Given that the review process will only be accessible to the drug companies (according to information provided by DoHA in a briefing on March 8, 2004), and that drug companies will appeal only against decisions that refuse to list a drug on the PBS or against prices being too low, the appeals process will create an upward bias in the prices Australians pay for their essential medicines.

Second, changes to IP laws will result in a delay in the introduction of generic medicines. The effectiveness of the PBS relies heavily on the availability of low cost comparators. Any delays in the introduction of generic pharmaceuticals onto the market will therefore result in increased costs to both consumers and to the Commonwealth Government. Representatives of the Department of Health and Ageing have conceded that, as a result of the FTA, delays in the introduction of generic pharmaceuticals can be expected.

Third, the agreed principles of Annex 2-c refer exclusively to the role of 'innovative pharmaceuticals' in the provision of 'high quality health care'. While there is no doubt that 'innovative pharmaceuticals' have an important role to play in the provision of health care it is also important to recognize the role played by health promotion, non-pharmaceuticals treatments and the price and availability of existing pharmaceutical substances in achieving improved health outcomes. The Australian PBS does not exist to reward 'innovative pharmaceuticals', it exists to allocate scarce health funding in the most cost-effective manner. Under current arrangements a new substance does not receive a premium because it is 'innovative', it receives a price that reflects its effectiveness in delivering health outcomes. It should not be seen as a coincidence that all four of the 'agreed principles' refer to innovation and R & D.

The Government continues to maintain that the FTA

preserves Australia's ability to maintain important public policy programs, including the affordability of medicines under a sustainable Pharmaceutical Benefits Scheme (PBS).

The Agreement does not impair Australia's ability to deliver fundamental policy objectives in health care and does not change the fundamental architecture of the PBS.

Australia will make improvements to the transparency and timeliness of PBS processes and Australians will benefit from faster access to subsidies for new prescription medicines.

While it is true that the 'fundamental architecture' of the PBS has been maintained it is also true that the effectiveness of the PBS has been eroded. When the details of the 'review process' are finally decided upon and the Medicines Working Group is established it is likely that further erosion of the effectiveness of the PBS will result.

While the Australian Government continues to maintain that the FTA will not increase the cost of pharmaceuticals, U.S. officials have been more forthcoming. As reported by John Garnaut in the *Sydney Morning Herald* (11 March, 2004) Republican Senator Jon Kyl described the FTA as a:

...“breakthrough” that began the process of getting other countries to bear a greater share of drug company research and development costs.

“One of the ways of addressing the causes [of high US prices] is to get the other countries of the world to help bear part of the burden of the R&D,” said Senator Jon Kyl, who lobbied Australian ministers on the Pharmaceutical Benefits Scheme last year. “So, my hat's off to your [Mr Zoellick's] team and the work that you did in at least beginning to address this with Australia.”

Senator Kyl said the final agreement, released last week, was only the beginning of negotiations over Australia's pharmaceuticals system.

"We don't need to discuss it here, but I know that there is much more work that needs to be done in further discussions with the Australians."

Impact of the FTA on the environment

While the Commonwealth Government has talked extensively about the benefits to the Australian economy, and in particular the benefits to Australian agriculture, that are likely to flow from the FTA there has been no discussion or analysis of the capacity of the Australian environment to cope with the production of billions of dollars of additional agricultural exports.

In fact, Australia is at the moment in the middle of a process to try and reconcile the competing claims that the agricultural industries already place on Australia's water and soil as well as the impact of land clearing on biodiversity.

In order to significantly expand Australia's agricultural exports it will be necessary to consume natural resources such as soil and water at an even faster rate than is currently the case. Given that the Commonwealth Government has conceded that action must be taken to reduce the amount of water being consumed by agriculture it is unclear how significant increases in agricultural exports are achievable.

Regional impact

According to the Regulatory Impact Statement which accompanies the Australia-US FTA:

Regions will be benefit (sic) from the opportunities created by the Agreement depending on the ability of regional exporters of goods and services to respond to these opportunities, and the contribution of tariff elimination to lower input costs, for example on agricultural machinery and fertiliser. Regions should also benefit from the impact of the Agreement in attracting additional investment from the United States, including in industries that will gain additional market access opportunities, for example, in the agricultural, mining and metals sectors.

It is almost inconceivable that the author of these words believe that they would convey useful information to either the Australian Parliament or the Australian people about the likely distribution of the costs and benefits of the Australia-US FTA between different geographic regions in Australia. While it is a truism to state that 'regions will benefit', it is also true to say that some regions will be adversely affected.

While the Committee may be awaiting further submissions based upon economic modelling, it is noteworthy that no modelling on regional impacts was carried out prior to the negotiations being completed. The Government has insisted that the FTA will be in the 'national interest', yet it has made this claim while completely unaware of the likely regional distribution of the costs and benefits of the agreement.

Conclusion

Australia's FTA negotiators were complicit in concealing the fact that Australia's PBS was a prime target for US trade negotiators. The negotiating team included experts on the PBS and industry insiders knew from day one that this was the case.

The current draft FTA includes changes to the PBS which will reduce its effectiveness. The Commonwealth Government continues to say that the 'fundamental architecture' remains unchanged, but these words have been carefully chosen to conceal the reality of the situation. The US negotiators demanded changes to the PBS in order to increase the profits earned by US drug manufacturers from sales in Australia and they were partially successful. Australian consumers and taxpayers will, by necessity, bear the cost of the US drug companies' gains.

More generally, the Australian negotiators did not seek information on the environmental, social or regional impact of the changes they were negotiating and no studies were commissioned. Prior to the commencement of the negotiations reports on

the overall economic impact and the likely response of our Asian neighbours were commissioned, the results of which were used to bolster the case for the agreement. While the Government is now in the process of arguing that social, environmental and regional factors weighed heavily in their consideration, the fact is that they could not have for the simple reason that information on the likely impacts on these issues is yet to be collected.