Impacts of the Australia-US Free Trade Agreement In Three Major Areas: Quarantine, PBS, Procurement

A Response to Questions on Notice from the Senate Select Committee on the AUSFTA

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In the hearings of the Select Senate Committee on the Free Trade Agreement between Australia and the United States of America, held in Sydney on May 4, 2004, we took a question on notice from Senator Boswell.

Senator Boswell asked us to provide the committee with details of 'the changes (we) perceive could occur and what (we) assess to be the most likely impact of those changes' in four key area: Quarantine, the Pharmaceutical Benefits Scheme (PBS), Government Procurement, and Intellectual Property (IP).

He also requested that we provide the 'scientific rigour' to back up our claims. As political scientists with experience in policy analysis and the politics of international economic relations, we have followed the methodological conventions of our discipline in compiling our response, basing our conclusions on a range of empirical materials, including both primary documents and secondary sources:

- The text of the Agreement itself
- Official statements by US and Australian Trade Representatives
- US and Australian Government policy documents and reports
- Other submissions to the Select Senate Committee on the FTA
- Official statements and reports of interest group organizations
- Public comments by business representatives
- Reports prepared by legal professionals
- Reports prepared by other academic experts.

As this is an adjunct to our original submission, we present our findings about the most likely outcomes of the deal in the form of scenarios (supported in each case by the relevant evidence):

(1) The scenario for the politicisation of Australian quarantine decisions
(2) The scenario for the dismantling of the PBS and increasing Australian drug prices
(3) The scenario for national losses arising from radical government procurement changes

Unfortunately, due to time constraints, we have not had an opportunity to address the issue of IP. We are, however, willing to do so if the Committee can afford us the time.

Scenario for the Politicisation of Australian Quarantine Decisions
(Chapter 7 of the Agreement)

> *When discussing Australia's quarantine regime with our trading partners I make no apologies for our conservative level of protection. As an island continent we are free from many of the pest and diseases prevalent in other parts of the world and our quarantine regime is designed to ensure that we stay that way … Quarantine decisions in Australia are, and will continue to be, made by AQIS in an impartial and objective manner – based on science ... as a nation that exports two-thirds of its agricultural produce, strong science-based international rules on quarantine - as exhibited in the WTO SPS Agreement - are very much in our national interest … Let me be very clear on this. Quarantine barriers are not something that the government will trade-off for any reason – be it in response to political pressure or to gain better market access for some other commodity.*
> (**Mark Vaile**, Australian Minister for Trade, QEAC and AQIS Seminar Canberra, 7 September 2000. Prior to his appointment as Trade Minister, Vaile had Ministerial responsibility for AQUIS*).*

Most significant change under the deal:
The inclusion of US Trade Representatives in Australia's quarantine decision-making processes will now give foreign trade officials the power to intervene in policies of utmost national importance for economic security.

Details of the change:
A stated objective of Chapter 7 is to 'provide a forum for addressing bilateral Sanitary and Phytosanitary (SPS) matters, resolve trade issues, and thereby expand trade opportunities' (Article 7.1). As such, two quarantine-related discussion bodies will be established under the Agreement:

(i) Australia-US Committee on Sanitary and Phytosanitary Matters (hereafter the SPS Committee),
and
(ii) Australia-US Standing Technical Working Group on Animal and Plant Health Measures (hereafter the SPS Working Group).

Both of these bodies are intended to 'facilitate trade between the parties'.[1]

The SPS Committee will comprise *trade representatives* as well as scientists.[2]

In the event of a trade-related quarantine dispute, the SPS Committee will refer the issue to the SPS Working Group. Within 60 days, the Group must devise a 'Work Plan' and 'conduct technical and scientific exchanges on the matter with a view to reaching consensus on resolution of the issue'.[3]

[1] 7.4 and Annex 7-A, Section A.1.
[2] '… representatives responsible for … sanitary and phytosanitary measures from … trade and regulatory agencies [will] participate in meetings of the Committee' (Article 7.4.6)
[3] Annex 7-A Section B.2

Most probable outcome of the change:
Australia will be forced to compromise its scientifically based quarantine decisions as a result of US trade pressure. Depending on the sector involved, this will:

(i) irreparably damage Australia's status as a disease-free agricultural exporter -- our key competitive advantage;
and
(ii) increase the use of toxic pesticides to decontaminate infested US imports, posing a health risk to Australians.

We will now present evidence to support the scenario of the politicisation of Australian quarantine decisions under the FTA.

Scenario -- Step 1:
The quarantine-related bodies established under the deal will be used by the US to pursue the reduction and elimination of Australia's quarantine standards, as they impinge on US exports.

Supporting Evidence:
We present 6 types of evidence to support the high probability of this outcome:
(i) Statements by US government officials
(ii) Statements by US farmer groups
(iii) Statements by Australian Government representatives
(iv) The reflection of US farmers' recommendations in the FTA text
(v) The placing of dollar values by US farmers on the gains expected to arise from the reduction and elimination of our quarantine standards
(vi) The reluctance of the US to pursue its quarantine complaints through the WTO's transparent dispute settlement mechanism

(i) Statements by US government officials:
Statements by US government officials reveal the *explicit intention* to use the bodies established under the FTA to pursue the relaxation and elimination of Australia's quarantine standards in a range of highly sensitive areas.

A February 8 USTR press release revealed the US government's belief that under the deal, 'Food inspection procedures that have posed barriers in the past will be addressed, benefiting sectors such as pork, citrus, apples and stone fruit'.[4]

The inclusion of pork in this statement is particularly concerning in light of Biosecurity Australia's recent decision to allow pork imports from the US, even though the CSIRO recommended otherwise.

The CSIRO report concluded that changes to quarantine protocols proposed by Biosecurity Australia would see a 94%-99% likelihood of an outbreak of the deadly post-weaning multi-systemic wasting syndrome in the next 10 years. Since its appearance in Europe only a few years ago, this disease has killed 8 million pigs, at a

[4] February 8, 2004, 'U.S. and Australia Complete Free Trade Agreement Trade Pact With Australia Will Expand U.S. Manufacturing Access to Key Pacific Rim Market' http://usembassy-australia.state.gov/hyper/2004/0209/epf104.htm

cost of $1.5 billion. It has no vaccination or cure; only Australia, Finland and Belgium are free from it.[5]

Fortunately, on May 13, 2004, a Senate Committee recommended that Biosecurity Australia's decision to allow importation of pork products be overturned, and that quarantine restrictions remain in place.[6] Importantly, the Senate Committee also criticised Biosecurity Australia for prioritising 'least trade restrictive' criteria in its Import Risk Analyses, even though Australia is not required to do so under its WTO obligations. As we argue below, this is illustrative of the extent to which trade considerations are *already* influencing what should be predominately science-based decisions.

(ii) Statements by US farming bodies:

According to their statements, US farmers believe that the bodies created under the deal provide a forum through which to pursue the 'reduction' and 'elimination' of Australian quarantine standards.

An American Farm Bureau Federation (AFBF)[7] report released in March 2004 stated clearly that increases in US agricultural exports to Australia depend on the 'reduction' and 'elimination' of our quarantine standards under the provisions of the deal:

> 'The draft [Free Trade Agreement] provides for follow-up talks on sanitary and phytosanitary measures … gains in United States exports of meats (particularly pork) and fruits and vegetables (including items such as citrus products, apples, and stone fruits) depends on the success of these sanitary/ phytosanitary talks.[8]

In fact, according to their statements, US Farmers expect their biggest export gains to come from the reduction and elimination of Australia's quarantine standards under the deal:

> It is critical to note that this increase [in exports] depends as much, or more, on progress in follow-up sanitary and phyto-sanitary talks on items such as Australia's quarantine and food safety regulations than on changes in Australia's low or zero tariffs … Failure to get these barriers removed will tip the scales considerably against expanded US exports to Australia.[9]

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[5] Hansard Transcript: Evidence presented by Dr Higgins, Chairman of Australian Pork Ltd, to the Senate Rural and Regional Affairs and Transport Legislation Committee: Import Risk Analysis for Pig Meat. March 8, 2004.

[6] Senate Standing Committee on Rural and Regional Affairs and Transport report on Biosecurity Australia's Import Risk Analysis for Pig Meat. May 13, 2004. http://www.aph.gov.au/Senate/committee/rrat_ctte/pork/report/report.pdf

[7] The Federation is popularly described as the 'Voice of American Agriculture', with over 5 million members nationally. Members are grouped under state branches (such as the Californian Farm Bureau Federation discussed below).

[8] American Farm Bureau Federation 2004, *Implications of An Australian Free Trade Agreement on US Agriculture.* p.3

[9] ibid.

(iii) Statements by Australian government officials.

The Government's SPS Fact Sheet states that under the deal:

> Australia's regulatory systems, ***risk assessment and policy development processes are not affected***, and the AUSFTA does not compromise Australia's quarantine regime (emphasis added).[10]

However statements by Australian government officials confirm that the bodies created under the deal will indeed impact on risk assessment processes and outcomes. Under questioning by the Select Senate Committee, the Department of Agriculture, Fisheries and Forestry representative was unable to deny this fact:

Senator O'Brien (Labor): '[The Committee] does not have any input into the import risk assessment process?'[11]
Ms Grenville (DAFF): 'I am not sure I would be comfortable saying exactly that.'[12]

(iv) The inclusion of US farmers' recommendations in the FTA text.

The proposal to place quarantine decisions under the scrutiny of trade representatives came directly from the California Farm Bureau Federation (CFBF). Their report clearly states that such a political forum would be critical to pursuing the elimination of Australian quarantine standards. Indeed, the creation of such a body was a precondition for US farmer's support for the deal:

> …[Australia's] burdensome phytosanitary restrictions are currently limiting export opportunities [so in order to increase export volumes] The California Farm Bureau Federation requests that…in addition to the standard WTO-based SPS language that is normally included in a free trade agreement…any FTA with Australia establish a standing SPS committee that will meet at least twice a year, and that would be under the direction of the US Trade Representative's office and their Australian counterpart. While technical regulators and scientists would of course be active participants, a policy level committee would help ensure that the technical and policy priorities are consistent and compatible…[13]

In this respect, Articles 7.4 and Annex 7-A appear to simply 'rubber stamp' US farmers' recommendations.

The fact that the relaxation of our quarantine standards was a precondition for US farmers' support for the deal is also reflected in the statement by the President of the US National Pork Producers Council: 'the support of US pork producers for the Australian free trade agreement is contingent upon Australia completing its technical work and opening its market to US pork'[14]

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[10] http://www.dfat.gov.au/trade/negotiations/us_fta/outcomes/17_sanitary_phytosanitary.html
[11] Hansard, Senate Select Committee on the Free Trade Agreement between Australia and the United States of America, 18 May 2004
[12] ibid
[13] CFBF Comments on U.S.-Australia Free Trade Agreement Before the International Trade Commission. Feb 2003. http://www.cfbf.com/issuesxs/trade/us-aus-fta.aspx
[14] NPPC Press Release, February 9, 2004: 'NPPC Support for Australia free trade agreement conditioned on commencement of u.s. pork exports'.

Clearly then, the relaxation and elimination of our quarantine standards is the *intended outcome* of the Agreement on the US side (and an outcome reluctantly *acknowledged unofficially* by Australian government officials).

(iv) US farmers have already placed dollar figures on the gains anticipated from elimination of our quarantine standards.

The fact that US farmers believe they will be successful in their quest to eliminate our quarantine standards is indicated by the fact that they have already put concrete dollar figures on the gains anticipated from this outcome:

> Assuming that progress is made in the sanitary/phytosanitary follow-up talks called for in the draft, United States exports of these commodities could expand $150-200 million over the intermediate and longer term. For example, United States exports of pork and poultry currently … are subject to sanitary and phytosanitary regulations that keep the trade volume minimal. With progress in sanitary and phytosanitary talks and improved market access, United States exports of pork could reach $50 million, with poultry exports reaching $25 million … With the elimination of tariffs and sanitary/phytosanitary restrictions on fresh and processed vegetables, fruits, and nuts, United States exports of $80 million over the l999-2001 period could increase by 50%, or $40 million.[15]

(v) The US is reluctant to raise its 'concerns' about out quarantine standards under the WTO's transparent dispute settlement mechanism.

If the US believes that our quarantine standards are unwarranted on scientific grounds and merely 'trade barriers in disguise', why not simply take it up with the WTO? There are two reasons.

(a) The US knows that the last WTO Trade Policy Review was supportive of Australia's science-based quarantine approach. Here is what the WTO had to say:

> Australia's SPS and quarantine requirements have been criticized by a number of its trading partners on the grounds that they are unduly stringent and therefore protectionist. But with Australia heavily dependent on agriculture and a major exporter of agricultural commodities and agri-food products, which receive relatively little government assistance and are sold at world market prices, these measures are believed to be necessary to ensure that Australia's reputation as a reliable exporter of high quality agricultural products is not jeopardized by pests and diseases.[16]

Indeed, Minister Vaile believed that the WTO's favorable review had put to rest the mistaken idea that our stringent quarantine standards are unnecessary barriers to trade:

> Mr Vaile said some WTO members had raised concerns during the review in areas such as Australia's strict quarantine system … "Many of these concerns are based on common misunderstandings and the review gave us an opportunity to challenge these head-on and explain why, for example, our science approach to quarantine is vital to Australia's national interest," Mr Vaile said.[17]

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[15] American Farm Bureau Federation 2004, *Implications of An Australian Free Trade Agreement on US Agriculture.* p.2-3

[16] WTO Secretariat Press Release, Australia's Trade Policy Review, 25 September 2002.

[17] Media release, Friday 27 September 2002 'Trading Partners Commend Australia's Trade Policies', Office of the Minister for Trade. http://www.trademinister.gov.au/releases/2002/mvt117x_02.html

(b) Because it knows that it is unlikely to be successful under the WTO, the US intends to use the new bilateral forum to 'resolve' all such issues – behind closed doors - before they reach the dispute stage.

In effect, the new arrangement will displace the WTO mechanism in favour of a non-transparent, bilateral forum operating in secret, giving US trade negotiators the power to shape nationally critical quarantine outcomes.[18] This is a concern shared by Australian Industry representatives, such as the Australian Chicken Meat Federation:

> Even though the US regards our quarantine as a non-tariff barrier, it has not challenged our cooked chicken meat protocol in the WTO. We believe the US may attempt to get quarantine through the back door through this FTA.[19]

It is worth recalling here the afore-cited statement by Mark Vaile in 2000, which clearly confirms that our national interest is well served by the existing WTO SPS Agreement:

> As a nation that exports two-thirds of its agricultural produce, strong science-based international rules on quarantine - as exhibited in the WTO SPS Agreement - are very much in our national interest … Let me be very clear on this. Quarantine barriers are not something that the government will trade-off for any reason – be it in response to political pressure or to gain better market access for some other commodity.[20]

Agreeing to provide a political forum outside the auspices of the WTO in which to discuss quarantine issues cannot be justified on national interest grounds.

Scenario -- Step 2:

The Australian government will find it extremely difficult, if not impossible, to resist US pressure to relax our science based quarantine standards.

Supporting evidence:

The fact that the Australian government *already* finds it very difficult (and often impossible) to resist US pressure to relax our quarantine standards - despite risks to animal, plant and human health in Australia – is evidenced by:

(i) the penetration of trade discourse - non-science issues - into Biosecurity Australia's risk-assessment processes; and
(ii) the reopening of existing quarantine protocols in the absence of changed circumstances or new scientific findings.

(i) The penetration of trade discourse into Biosecurity Australia's (BA) risk-assessment processes

The idea that Australia's scientifically-based quarantine system is at risk of becoming politicised is not new or radical – a Senate Inquiry into this very issue was held in

[18] While WTO dispute resolution panels operate in confidence, the existence, nature, and outcome of the trade dispute is open to public scrutiny. This will not be the case under the AUSFTA.

[19] Dr. J.Graham, Exec Director, Australian Chicken Meat Federation, DFAT, Senate Submission on AUSFTA, 24 July 2003 p. 369.

[20] Mark Vaile, Australian Minister for Trade, QEAC and AQIS Seminar Canberra, 7 September 2000. Prior to his appointment as Trade Minister, Vaile had Ministerial responsibility for AQUIS.

April this year, following BA's decision to allow Banana imports from the Philippines on scientifically questionable grounds.

During this Senate Inquiry, compelling evidence was presented to indicate the penetration of trade discourse into Biosecurity Australia's risk-assessment processes. For example, the testimony of Mr David Peasley, Member of the Risk Analysis Panel,[21] revealed that all stakeholder meetings in Australia regarding the Banana Import Risk Analysis started with a presentation on Australia's international trade position and obligations. This highlights the impact that trade pressures (i.e. non-science matters) are *already* having on the framing of quarantine discussions in Australia.

The aforementioned criticism of Biosecurity Australia by the Senate Committee investigating the pig meat import decision is also illustrative of the extent to which trade considerations are *already* influencing what should be entirely science-based determinations. Recall that the Senate Committee found Biosecurity Australia had been prioritising 'least trade restrictive' criteria in its Import Risks Analyses, even though Australia is not required to do so under its WTO SPS obligations.[22]

The fact that Biosecurity Australia is wary of exercising its rights under the WTO SPS Agreement is extraordinary – especially as Australia has so much to lose in this area. As we detail below, the WTO has acknowledged the fact that, as an island nation, Australia has a unique disease-free status to protect, and is well within its rights to exercise precaution in quarantine decisions. For some reason, however, Biosecurity Australia has begun to operate as if it had no option but to pursue 'harm 'minimisation' instead of 'zero risk':

> *'We don't have the option of zero risk here. We do manage risk to a very low level, but if we were to operate a zero risk policy, then there would be no trade or tourism'*[23]

This is a curious statement coming from an Australian official, especially when the US – which has far less to lose than Australia in this area -- has explicitly stated that its states are allowed to adopt a zero risk policy if a real risk to plant, animal or human health can be demonstrated scientifically. In the words of the US Trade Representative:

> The NAFTA and WTO agreements ensure that state and local agencies continue to have an absolute right to set … environmental, health and safety standards at the levels they consider appropriate, **including zero risk levels if they so choose**, provided that the standards are transparent and are not used a disguised barriers to trade.[24]

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[21] *Submission to the Senate Inquiry into Philippines Banana Import Risk Assessment*, pp.1-2, 2004

[22] Senate Standing Committee on Rural and Regional Affairs and Transport report on Biosecurity Australia's Import Risk Analysis for Pig Meat. May 13, 2004. http://www.aph.gov.au/Senate/committee/rrat_ctte/pork/report/report.pdf

[23] Mary Harwood, Biosecurity Australia: ABC 7.30 Report. TV Program Transcript Location: http://www.abc.net.au/7.30/content/2004/s1051626.htm Broadcast: 23/02/2004

[24] USTR written response to California legislators, letter dated March 26, 2001, available at: *www.sen.ca.gov/ftp/sen/committee/select/INTER_TRADE/home/USTRLETTER_ANALYSIS.HTM*

The fact that the Agreement on the table will see trade officials included in quarantine discussions between Australia and the US is also illustrative of the penetration of trade discourse into what should be exclusively science-based decisions.

(ii) The reopening of existing quarantine protocols in the absence of changed circumstances or new scientific findings

The fact that the Australian government *already* finds it difficult (and often impossible) to resist US pressures to relax quarantine – even when the science dictates otherwise, is evidenced by the recent reopening of a range of existing quarantine protocols in the absence of changed circumstances or new scientific findings. In addition to the case of bananas, consider meat imports.

BA's decision to drop quarantine restrictions on North American meat imports (ending the 30-day quarantine period) is just one further example of bowing to US trade pressure. Cattle Council of Australia Executive Director, Justine Toohey argues that this will 'raise the risk of foot and mouth and other cattle diseases entering the country through contaminated meat'.[25]

Trading off increased risk to agriculture with increased risk to human health and environment:

One of the most worrying aspects of the erosion of quarantine protocols is the trade-off in human health that it requires: in order to approve the importation of produce from diseased areas, the Australian government makes this conditional upon 'decontamination' with Methyl Bromide.

Methyl Bromide – a known carcinogen – is one of the most toxic chemicals known to human kind. The BA website says that:

> Methyl bromide is an extremely toxic, odourless gas. Regulations in some countries (or states) may specify that methyl bromide used in fumigation treatments must contain a warning agent … For the purposes of quarantine treatments, and where permitted, 100% methyl bromide should be used when ever possible. This is an extremely toxic substance. Its use should be subject to strict occupational health and safety standards to protect the people that are working with it as well as those who may be inadvertently exposed to it.[26]

Methyl Bromide is also the largest existing contributor to Ozone Layer depletion in the world today – 60 times more damaging to the ozone layer than CFCs, which are already banned:

> Methyl bromide is an ozone depleting substance (ODS). Its use eventually results in a complex set of chemical reactions that destroy the ozone layer … If this destruction is not halted, depletion of the ozone shield will have grave consequences for human health, for our food production systems and, ultimately, for the ecosystem that supports life on Earth. Methyl bromide is a potent ozone-depleting chemical. According to the Montreal Protocol's Scientific Assessment Panel, each atom of bromine from methyl

[25] *Australasian Business Intelligence*, 4 Dec, 2002, David McKenzie.

[26] AQIS quarantine treatments: Aspects and procedures. Part B (i) - Methyl Bromide Fumigation Standard. http://www.affa.gov.au/content/output.cfm?ObjectID=D2C48F86-BA1A-11A1-A2200060A1B01673

> bromide that reaches the stratosphere destroys approximately 60 times more ozone than each atom of chlorine from CFCs.[27]

Because of the dangers inherent in using this deadly toxin as a pesticide, in 1997 the Parties to the Montreal Protocol on Substances that Deplete the Ozone Layer mandated the phasing out of the production and use of the chemical in all developed countries by 2005, and in all developing countries by 2015.

> Under The Montreal Protocol of 1991, methyl bromide was defined as a chemical that contributes to depletion of the Earth's ozone layer. The definition was based on scientific data. Accordingly, the manufacture and importation of methyl bromide will be phased out in developed countries as follows: 25-percent reduction in 1999, 25-percent reduction in 2001, 20-percent reduction in 2003, and complete phase out in 2005. In developing countries, consumption will be frozen in 2002 at 1995-98 average levels, followed by 20-percent reduction in 2005 and complete phase out in 2015. Exemptions for developed and developing countries include quarantine, critical uses and certain preshipment uses.[28]

As Biosecurity Australia reported above, Australia should be *minimising* the application of methyl bromide where ever possible, not increasing its use. However the recent decisions to overturn existing bans and import a range of diseased produce from the US and elsewhere have all been on the condition that the produce is drenched with Methyl Bromide:

Grapes

In February 2002, BA lifted a 10-year ban on California Table Grapes, in spite of the risk of spreading Pierce's Disease and glassy-winged sharp shooters. Condition of importation: fumigation with methyl bromide.[29]

Citrus

BA recently decided to allow Florida citrus fruit into the country – in spite of a study which identified 20 known pests or diseases – such as citrus canker – which can be brought in via the fruit.[30] Condition of importation: fumigation with methyl bromide.

Pineapples

BA recently decided to allow importation from the Philippines and elsewhere, despite the identification of a range of exotic pests (such as mealy bugs) and weeds with the potential to cause significant damage to Australian crops. Condition: fumigation with Methyl bromide, to be permitted on Australian Soil.[31]

Bananas

BA recently overturned the decision to allow banana imports from the Philippines, again conditional on fumigation with Methyl Bromide. (Note that Philippine banana

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[27] United Nations Environment Programme (UNEP) and United Nations Industrial Development Organization (UNIDO) Methyl Bromide Alternatives Project. FAQs: Why is Methyl Bromide Harmful? http://www.uneptie.org/ozonaction/unido-harvest/faq.html

[28] United States Department of Agriculture. Methyl Bromide Homepage: http://www.ars.usda.gov/is/mb/mebrweb.htm#why

[29] 'Augmented quarantine import conditions for the entry of table grapes: PBPM 2002/05'. Biosecurity Australia Plant Biosecurity Policy Memorandum 2002/05 - Import Risk Analysis - Fresh Table Grapes from California.

[30] *Australasian Business Intelligence*, 16 July 2003, D. McKenzie.

[31] Pineapple IRA: Final IRA Report, Biosecurity Australia p. 46

export businesses are majority US owned). This would have required the use of Nearly 20 tonnes of the poisonous chemical annually.[32]

This new habit of reopening existing quarantine protocols in the absence of changed circumstances or new scientific findings led directly to the establishment of the aforementioned Senate Inquiry:

> The Australian Democrats are calling for a broad inquiry into the integrity of Australia's quarantine system. Last week Biosecurity Australia made the decision to allow Filipino bananas, New Zealand apples and American pig meat to be imported into the Australian market. Democrats Agriculture spokesman, Senator John Cherry, says the quarantine watchdog seems to be moving away from a strict, science-based system, and he would like a Senate inquiry to find out why. "We need to get to the bottom of that, as to why Biosecurity Australia are now accepting a level of risk of disease coming into Australia much higher than farmers, consumers and probably the Australian public as a whole would have been prepared to accept in the past," he said. Senator Cherry says the free trade agreement with the US has led to trade officials being involved in quarantine decisions, which were previously only made by scientists. "Certainly our concern is that the only role trade officials from the US could possibly play in our quarantine system in a technical working party is trying to put pressure on, more political pressure to lower our quarantine standards, and increase the risk of diseases coming into Australia from other countries," he said.[33]

Under the deal then, we can only conclude that the risk to plant and animal life will be increased in a number of instances. In others, it will be increasingly traded against a higher risk to human health, by allowing imports of pest- and disease-prone produce on condition of heavy fumigation with toxic chemicals such as Methyl Bromide. The future of our agricultural industry and exports, our native environment and health does not augur well under the new Quarantine system created by the deal.

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[32] ABGC Press Release 'Toxic chemical fumigation required to make imports "safe"' http://www.abgc.org.au/pages/media/031013_112905.asp.
[33] ABC News Online Feb 29 2004: http://www.abc.net.au/news/newsitems/s1055793.htm

Scenario for National Losses
from
Radical Changes to Government Procurement

Chapter 15 of the Agreement

Most significant changes under the deal:

(1) Abandonment of industry development programs: Chapter 15 removes mandated preferential arrangements that underpin the growth of new high-value added Australian industry, such as the information and communications technology sector. The deal stipulates the removal of all offset conditions that require winning tenderers to source local inputs or upgrade technology to support Australian manufacturing, services, and jobs. It also prohibits seeking or taking account of offsets in the award of contracts.[34]

(2) Permission to bid for US government procurement contracts at both the Federal and State level. Australian bidders will no longer be required to have a branch office in the US, and the 'Buy American Law' penalty of 6%-12% on Australian bids will be waived.

(3) Far-reaching changes to Australia's Procurement regulations to bring them into line with US standards. This relates particularly to making the bidding and award process more 'transparent'. The reforms effectively reverse a trend in Australian government procurement regulation which has been to move away from rigid process and procedure controls to a more cost-effective system of prescribing the outcomes to be achieved.[35]

Most likely outcomes of these changes:

The three most likely outcomes of these changes are:

(1) The loss of an indispensable industrial promotion tool (but its broad retention in the US through creative, non-transparent and other regulatory measures);
(2) The inability of Australian firms to compete in the US market due to a number of non-transparent and regulatory barriers, both new and existing; and
(3) A major regulatory and financial burden on Australia to comply with the new procurement measures.

The abandonment of mandatory offset and industry development provisions, together with the much more protective environment in which our firms will have to compete, and the costs of compliance with new regulatory requirements will combine to bring about a net outflow of resources from Australia.

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[34] Article 5 of chapter 15 says: …the procuring entity may not seek, take account of, impose or enforce offsets in the qualification and selection of suppliers, goods or services, in the evaluation of tenders or in the award of contracts, prior to or in the course of a procurement process. ' Offsets mean any conditions which stipulate use of domestic content or supplies, licensing of technology transfer, investment, counter trade or similar actions to encourage local development.

[35] Tom Brennan & David Hodges *Government Procurement Impacts of the Australia-United states Free Trade Agreement,* Corrs Chambers Westgarth: Sydney, 11 May 2004, p.14. The changes to procurement methods are spelt out in several articles. Article 15.11 on the Domestic Review of Supplier Challenges makes clear the substantial reform to procurement processes that Australia will be required to undertake to deal with appeals and complaints by aggrieved tenderers. Should these reforms not be undertaken, and therefore an obligation under the FTA not be implemented, Australia would be open to dispute settlement proceedings instituted by the US under Article 21.11.

Scenario—Step 1

(1) The loss of an indispensable industrial promotion tool.

The deal excludes government agencies from using procurement contracts in any way that would enhance local industry development, source local resources, promote Australian business, or give preference to local suppliers and employment.

Thus, for example, 'The endorsed supplier arrangement conducted by the Department of Finance and Administration at the Commonwealth level will…no longer include industry development requirements. There can be no requirement for domestic content, domestic supplies, the licensing of technology transfer or similar actions taken into account when making a choice of supplier. This will see the abolition of a mandated component in the information and communications technology areas[36] (known widely as the 'Microsoft Clause'!).

The current price preference arrangements that exist for Australian- and New Zealand- sourced goods and services under an inter-governmental agreement on procurement would also be terminated should the States and Territory agree to comply with the Chapter. Under the deal, the States would no longer be able to give preference to Australian or New Zealand suppliers in IT outsourcing contracts.[37]

More generally, removal of the 'Buy Australian' core of government procurement policy will occur at the same time that US purchasing norms are making 'Buy American' provisions more pervasive. Both changes, taken together, will have damaging consequences for Australian business, government and community. *They will turn what is currently a net gain for the country (Australian taxpayer dollars invested in upgrading local skills and enterprise) into a net loss for Australian industry and jobs (transfer of Australian taxpayer dollars to American companies).*

Scenario – Step 2

(2) Inability to compete in the US market due to hidden and growing regulatory barriers

The most significant change -- theoretically, in Australia's favour -- would be to remove the price penalty from bids by Australian-based suppliers.

However, realistic assessments indicate that access to the US procurement market is, in practice, likely to be severely restricted by the operation of a number of significant barriers and therefore most likely to be of marginal significance to Australian firms. These barriers include:

(i) The operation of the US Offsets for Small Business Program
(ii) The use of highly specialized, complex and technical processes in US government procurement
(iii) Legislation to strengthen the Buy American Act (BAA) of 1933
(iv) Blurring the lines between Acquisition and Procurement
(v) Growth of informal barriers, non-transparency, etc., post 9/11.
(vi) Evidence of informal pressure of BAA being applied throughout the network of US procurement agencies

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[36] Tom Brennan & David Hodges, *Government Procurement Impacts of the Australia-United States Free Trade Agreement*, Corrs Chambers Westgarth, 11 May 2004, p. 15.

[37] Ibid.

Supporting evidence for each of these barriers is examined in turn.

(i) The operation of the US Offsets for Small Business Program

The United States has carved out a right to continue its offsets for Small business program under the Chapter 15 of the FTA.[38] On DFAT's own estimate, this is likely to significantly impair access of Australian suppliers to American procurement markets. Indeed, given the importance of the US offset program, it is 'conceivable that Australian export growth' resulting from the procurement chapter 'could be confined to niche markets where there is no significant US small business competition'.[39] This was the conclusion of DFAT in 1997 in considering the pros and cons of joining the WTO's Government Procurement Agreement. It remains valid today.

Implications of different national definitions of 'small' business. Part of the reason for DFAT's conclusion relates to how the US defines 'small business' – in effect covering a vast array of relatively large enterprises. It is true that both countries agree to exempt 'small business' from the restrictions of Chapter 15. However, the vast disparities in how 'small business' gets defined in the different jurisdictions -- up to 1500 employees in the US, compared with less than 200 in Australia -- means that most of the procurement areas in which Australian companies could compete would be set aside for American firms.[40] By contrast, given the much lower size threshold that prevails in Australia, a much larger slice of the Australian procurement market would now be opened up to US firms.

We note the striking fact that the Canadian provinces -- motivated in part by concerns about opening up procurement in health and education to US suppliers -- have refused to sign up to deals negotiated by their federal Government that allow Americans to retain the Buy American and small business set-asides.[41] Set-asides in the US work thus:

> The Federal Government often provides funds to state and local governments with the requirement that the money be spent on suppliers and products that have a certain minimum proportion of US content. This is allowed under both the GPA and NAFTA because it is *not a direct purchase of the Federal Government that is covered by the Agreements*. For example, the Transportation Equity Act for the 21 Century (TEA-21), which provides financing for transit, highway, and airport projects carried out by state and local governments and private sector organizations, has Buy American provisions that require all steel and manufactured stock to be 100 per cent American content and all rolling stock to be 60 per cent American and assembled in the US. The small business 'set-asides' are Federal Government procurement preferences in the United States that reserve a certain proportion of government contracts for small business. These set asides are large, amounting to [at least] 23 per cent of the Federal Government's contract budget, and have usually been met or exceeded. And the US businesses benefiting are not so small either by Canadian standards, having as many as 500 employees in manufacturing (even 1,500 in some sectors) and revenue of up to US$17 million in services [as at 1998].[42] (*emphasis added*)

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[38] Annex 15 –G Schedule for the United States Clause 1.

[39] Department of Foreign Affairs and Trade, WTO Agreement on Government Procurement; Review of Membership Implications (1997).

[40] http://www.sba.gov/size/indexsize.html (averaging 500 employed in manufacturing and mining, US$6 million for most retail and service industries).

[41] Patrick Grady and Kathleen Macmillan 'Taming Procurement' in Seattle and Beyond: the WTO Millenium Round (1999), Ch. 5 CORRECT PUBL DETAILS??

[42] Ibid.

Further significant procurement market barriers include:

(ii) The use of highly specialized, complex and technical processes in US government procurement.

Processes such as the Invitation For Bids (IFB) and Request For Proposals (RFP) process -- are considered costly and daunting for new entrants. Since American firms are already familiar with their own system, it is clearly Australian firms which will be disadvantaged.

Moreover, US procurement arrangements may operate as an informal trade barrier in so far as 'without established and substantial government bid infrastructure' and in the absence of 'opportunities for teaming with established US-based suppliers' the likelihood of succeeding through those processes 'is not high'.[43]

(iii) Legislation to strengthen the Buy American Act of 1933.

This was enacted 70 years ago to ensure that Federal procurement policies support American industry and jobs. **The Buy American Improvement Act** – introduced in both houses, now referred to the House Committee on Government Reform for further action – aims to tighten the BA Act by restricting its five primary waivers. Key provisions of the bill would:

- Close loopholes in the current waiver authority in the BA Act by restricting its five primary waivers.
- Increase the minimum 'American-made content' standard from 50 to 75%,
- Give US producers preference if the US bid is substantially the same as the foreign company's bid, or the US company is the only US producer of the goods or product.
- Encourage US procurement at US Embassies and military bases for overseas use on routine, non-emergency purchases.
- Require each agency to file annual report with Congress, providing an itemized list of all BAA waivers, dollar values, and sources – to be made available on the internet;
- Develop consistent, government-wide definitions of terms commonly used to invoke waivers "inconsistent with the public interest', 'unreasonable cost', etc.)[44]

As one industry consultant noted in an interview, '…if they want every contracting officer to report every part, country of origin, price, the reason they bought it, and so on, then they [US government agencies] would avoid buying anything with foreign content just to avoid having to do the report.'[45]

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[43] Tom Brennan & David Hodges, *Government Procurement Impacts of the Australia-United States Free Trade Agreement*, Corrs Chambers Westgarth, 11 May 2004, p.14.

[44] US Senator Russ Feingold on the Buy American Act, July 29, 2003, http://feingold.senate.gov/speeches/03/07/2003820902.html; The Orator.com News & Information, 108th Congress, 2d Session, In the House of Representatives, January 28, 2004, Buy American Improvement Act of 2004. http://www.theorator.com/bills1108/hr3741.html

[45] Amy Svitak, 'Negotiations under way on Defense 'Buy American' Deal' 12 September 2003, www.GovExec.com.

(iv) US Government purchasing policy blurring the lines between Acquisition and Procurement

The US government draws a distinction in its purchasing strategy between 'acquisition' and 'procurement'. The distinction would appear significant: while both involve government purchasing, 'procurement' requires conventional tendering that is open and transparent; 'acquisition' does not.[46] Evidence indicates that US government is seeking to re-badge more of its purchasing requirements under 'acquisition', thus removing it from the regulatory burdens of procurement.

For example, the bulk of the enormous budget of the newly constituted Homeland Security, will be dedicated to Buy American policies. Although procurement has some place in the agency's purchasing policy, US procurement commentators report that 'the real meat of the department's buying strategies is spelled out in the section on technology acquisition'. Similar trends can be seen in the practices of other agencies, including the Energy Department, Coast Guard, and Transportation Security Administration.

> **'**Such agencies as the Coast Guard and the Transportation Security Administration have awarded creative, flexible contracts that have broken the mold of traditional government procurement. TSA's purchasing is based on an acquisition model that puts responsibility for the contract's success more on the vendor than on the agency. White House officials have heralded it as a model for Homeland Security.[47] (emphasis added)

'Acquisition' advocates – are currently aiming to extend the practice beyond the science and technology arena. While there is a debate between those who want to see acquisition extended and those who call for caution on the grounds that it requires a different set of skills, there is widespread support for a model of acquisition that has been institutionalized in the military. [48]

(v) Growth of informal barriers, non-transparency, etc., post 9/11.

In the US technology procurement markets, 'large contractors such as Lockheed Martin, Northrop Grumman and Computer Sciences Corp., which lead teams of other companies on the biggest technology contracts in government, exert even more influence over the procurement process than they did before Sept. 11…. For now, the agencies are relying heavily on trusted vendors with proven track records.'[49]

At the same time that the federal market is booming with new spending, the contracting process has veered away from open and transparent tendering. White House officials, lawmakers and some industry lobbyists have been objecting to the improper use of government-wide technology contracts, popular deals that are pre-awarded to companies and then opened up for all agencies to use. Reports by some

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[46] The official justification for this distinction is that acquisition work requires long-term planning, that it is focused on technologies that aren't necessarily commercially available.

[47] Shane Harris, Tech Insider 'The Buying Game', 15 March 2003. www.GovExec.com

[48] ibid.

[49] Shane Harris, 'Information Technology: Waiting for the Spending Boom', 15 August 2003, www.Gov.Exec.com

agency inspectors general found that acquisition personnel often don't conduct full competitions on the contracts.[50]

For example, only after vigorous protests had been launched by Beretta (an Italian handgun supplier to the U.S. military) and other firms did the Transport Security Administration 'drop narrowly drawn contract specifications favorable to US manufacturer Smith & Wesson and open up the competition industry-wide'.

Questions in Congress over the handgun contract have drawn attention to the TSA's broader contracting practices, particularly its apparent tendency to avoid competitive bidding for its contracts. A member of the House Homeland Security Appropriations Subcommittee found that the TSA, in little more than a year since its inception, awarded without calling for tenders more than 90 contracts valued at over US$50 million. 'The agency also invoked an arcane "Buy American" executive order that made guns from Italian (Beretta), Austrian (Glock) or other foreign firms ineligible, but exempted Russian- and Chinese-made weapons.'[51]

(vi) Evidence of pervasive informal pressure to apply the Buy American Act throughout the network of US procurement agencies:

Even where suppliers are from countries signatory to the GPA under the WTO, there is evidence that 'Buy American' preferences are being exercised. Two recent cases involve effective pressure to revoke contracts granted to German manufacturers of handguns for use by airline pilots and to British manufacturers of berets for US troops. In each case, Congressional intervention resulted in an overturning of foreign tender awards in favour of US suppliers.[52]

Outspoken advocates of the Buy American Act make it clear to the relevant agencies as to whom their procurement decisions should favour. When the Bureau of Immigration and Customs Enforcement was about to award 'a substantial contract' (worth some US$30 million) to supply handguns to its officers, the agency was instructed by the chairman of the House Ways and Means Committee 'to strongly consider American companies when making that award'. It did. A few days before the hearing, the Defense Logistics Agency canceled all the contracts involving foreign suppliers.[53] As Japan's METI (Ministry for Economy, Trade and Industry) has observed of the US on a number of occasions, 'preferential treatment for domestic products is a basic policy of the federal government'.[54]

In sum, the oft-repeated claim that Australian firms will gain significant benefit from access to a large US procurement market has little basis in fact. As far as the evidence indicates, the most that Australian firms can expect are 'crumbs from the feast'. In view of the well-documented obstacles, not to mention the likelihood of new ones (a

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[50] ibid.

[51] Richard Sia, 'TSA handgun contract draws ire of firearm makers', 16 July 2003, www.GovExec.com.

[52] Richard H.P. Sia, 'TSA revisits German gun contract'. *Congress Daily*. 30 July 2003; A. Svitak 'Negotiations under way on Defense "Buy American" deal'. *Congress Daily*. September 2003; Svitak 'DoD working with lawmaker to settle "Buy American" dispute'. *Congress Daily*. 17 September 2003.

[53] Sia, 'TSA revisits German gun contract' *Congress Daily*, op.cit.

[54] Japanese Ministry for Economy, Trade, and Industry. http://www.meti.go.jp/english/report/data/gCT9913e.html

strengthened Buy American Act), we concur with DFAT's earlier conclusions and the view of legal experts that 'there is no reason to think that it [Chapter 15] will lead to a substantial flow of business opportunities to the generality of Australian exporters'. [55]

Finally, we predict a very large regulatory and financial burden on Australia in having to comply with the new regulatory measures. Since Australia is the one that is being required to conform to the other bilateral partner's norms, it will bear the brunt of the burdens.

Scenario – Step 3

(3) Increased burdens – costly in time, money, and resources -- associated with far-reaching changes to Australia's regulatory arrangements to make them conform to US procurement requirements.

Implementation of the Government Procurement Chapter in Australia will involve extensive changes to the procurement process and thus to our domestic regulatory arrangements in order to comply with the terms of the FTA. (By contrast, the US will need to make only minor adjustments).

The main regulatory changes will involve:

- Strict controls on the use of selective tendering and other restricted procurement strategies.
- Procurement authorities obliged to provide information to all unsuccessful tenderers on the reasons for not succeeding**.**
- Substantial expansion of tenderers' rights and scope for legal challenge to government procurement decisions. Unsuccessful tenderers to have a right to judicial review of procurement decisions in the courts; courts to have the capacity to make interim orders to ensure the position of unsuccessful tenderers is not prejudiced.[56]

Impacts of the changes

This will entail a radical change to the procurement process; it will overturn a relatively streamlined and cost-effective process in favour of one that will usher in increased regulatory burdens, more litigation, and thus higher costs all-round for Australian tenderers, government agencies, and taxpayers. In particular, the changes to procurement procedures entail:

- Reversal of an efficient, cost-effective procurement system for 'process prescriptions far more extensive and onerous than have applied in the Commonwealth for over 20 years'. [57]
- Substantial burdens in costs and delays both for local suppliers and buying agencies, potentially at the mercy of disaffected, cashed-up corporations. Procurement decisions will be reviewable by the Courts, who will have the power

[55] Tom Brennan & David Hodges, *Government Procurement Impacts of the Australia-United States Free Trade Agreement,* Corrs Chambers Westgarth, 11 May 2004, p.13.

[56] Tom Brennan 'Government Procurement'. *Review of the Free Trade Agreemen*t, Corrs Chambers Westgarth, Sydney, 10 March 2004, p.23

[57] Brennan, *Review of the Free Trade Agreement*, op.cit. p.25.

'to prevent the awarding of a contract or the performance of a contract which has been awarded in order to protect the position of a complaining tenderer'.[58]

- Disadvantaging in particular Australian and NZ suppliers (with fewer resources and government subsidies).
- Proliferation of appeals and of courts and tribunals dealing with procurement (estimated average cost of appeal 10 years ago was c. $US60,000; real costs in recent Australian appeals estimated to be 15 times higher.)[59]

The incorporation of US dispute processes into procurement practice, thus establishing a formal bid challenge system, is an aspect quite foreign to Australian experience. As DFAT concluded in its 1997 report on the implications of joining the WTO's GPA, the bid challenge is likely to substantially increase costs and delays both for suppliers and buying agencies, working particularly to disadvantage Australian suppliers. In DFAT's own words,

> …on the issue of increased costs and delays, there is some evidence from [WTO GPA] countries that there is reasonable cause for concern about this issue but there are a variety of options available for the management of the appeals process to keep costs down and speed the review process up where that is necessary. Where procurement challenge arrangements can be costly, they need not always be so even from cases that are taken through a full formal appeal process. In Canada in particular, where there is a relatively informal regime, the cost to both suppliers and government are quite small. *In the US, in contrast, where the procurement challenge is more complex, the average cost of appeal…was estimated in 1994 by officials to be about US$60,000.*[60] (emphasis added)

Conclusion

Australian firms' access to the US procurement market will be severely limited by a number of barriers and discriminatory policies**.** A major barrier discussed here is the fact that the US government has retained the right to give preference to its 'small' firms -- which are not small at all -- employing up to 1,500 people. This effectively locks out the vast majority of Australian firms from the US procurement market. Conversely, since Australia's small business procurement programs only apply to firms with fewer than 200 employees, a much higher percentage of US firms will have access to the Australian procurement market. The pervasive norm of 'Buy American' is another barrier that will reduce access to the US market, as evidenced in the recent overturning of contracts awarded to foreign suppliers, in spite of their governments being signatories to the WTO GPA. As we have also seen, a growing trend to award contracts without competitive bidding is a further indication of the existence of protective barriers to the US procurement market.

Under these highly uneven circumstances, the benefits of Chapter 15 are likely to flow in one direction – towards the United States. While the burdens – radical regulatory changes, the heavy costs of litigation and time delays for government agencies and domestic suppliers – will fall heavily on Australia, and not least on the Australian taxpayer.

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[58] ibid. p. 24.
[59] Ibid. p. 12.
[60] Department of Foreign Affairs and Trade, WTO Agreement on Government Procurement; Review of Membership Implications (1997).

Scenario for the Dismantling of the PBS and an Increase in Australian Drug Prices

Annex 2-C- Pharmaceuticals and Chapter 17 – Intellectual Property Rights

Most significant changes:

(1) **The explicit prioritisation of policies that support and reward the 'innovation' and 'research and development' activities of pharmaceutical companies**.[61] This reverses the fundamental policy goals of the PBS, which is to ensure the affordability of therapeutically effective medicines for all Australians. This goal is virtually absent from the Chapter and completely excluded from the important 'Exchange of Letters on the PBS' between Minister Vaile and USTR Zoellick.[62]

(2) **The creation of a new review process to independently assess contested listing decisions of the Pharmaceutical Benefits Advisory Committee (PBAC).** While the stated aim is presented in the acceptable language of increasing the 'transparency' of the PBAC decision-making process,[63] and prioritising 'innovation', the intended aim of this provision is to provide pharmaceutical companies with a lever to systematically contest PBAC determinations and increase the rate of new drug listings. The intended thrust of the change emerges clearly from the vigorous targeting of the PBAC as a 'market access barrier' by the US Pharmaceutical lobby group, PhRMA, in its most recent submission to the United States Trade Representative.[64]

The overwhelming emphasis on increased 'transparency' and 'innovation' in the Agreement must be understood in this context. By agreeing to allow an independent

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[61] Article1 of Annex 2-C commits the Australian government to recognising and prioritising the following principles:

(a) 'the important role played by innovative pharmaceutical products in delivering high quality health care;

(b) the importance of research and development in the pharmaceutical industry and of appropriate government support, including through intellectual property protection and other policies;

(c) the need to promote timely and affordable access to innovative pharmaceuticals through transparent, expeditious, and accountable procedures, without impeding a Party's ability to apply appropriate standards of quality, safety, and efficacy; and

(d) the need to recognize the value of innovative pharmaceuticals through the operation of competitive markets or by adopting or maintaining procedures that appropriately value the objectively demonstrated therapeutic significance of a pharmaceutical'.

[62] The 'Exchange of Letters on the PBS (Vaile-Zoellick) makes explicit that the sole purpose of the changes to the PBS is 'In order to enhance transparency, meaningful consultation,and accountability in the process of selecting, listing, and pricing of pharmaceuticals under its …(PBS).'

[63] Article 2(f) compels signatories to 'make available an independent review process that may be invoked at the request of an applicant directly affected by a recommendation or determination.'

[64] Excerpt from PhRMA's 2003 Submission to the US Trade Representative on Australia, http://www.cptech.org/ip/health/c/australia/phrma-au-2003.html PhRMA was concerned that the PBAC rejected 40% of major applications for new listings in 1997 and 59% in 1998. It alleged that PBAC decisions tend to 'diminish the intellectual property rights granted to innovative pharmaceutical and biotechnology products'. It also claimed that the Pharmaceutical Benefits Pricing Authority (PBPA) (which sets the prices for drugs approved for listing by the PBAC) uses non-transparent pricing practices and thereby 'seriously erodes intellectual property protection, devalues innovation, and discourages investments in new medical discoveries'.

review of PBAC determinations, the deal clearly gives primacy to the marketing interests of the US Pharmaceutical lobby, and thereby subverts the national interest enshrined in the PBS.

(3) **The extension of pharmaceutical patent protection via new data protection measures[65] and measures relating to delays in marketing approval and the marketing of generics[66].** The context for this change is highly instructive. US Pharmaceutical companies have been pushing for the extension of patent protection more vigorously of late because generics companies are about to capitalise on opportunities offered by patent expiry on $100bn worth of revenues by 2005 (based on 1999 sales). The generics industry has been identified as 'a new threat' to the Pharma sector's monopoly profits.[67] Australia's Department of Industry Tourism and Resources identified at least 16 popular drugs whose patent is about to expire in the next couple of years and who would benefit directly from Patent extensions under the FTA.)[68]

Most probable outcomes of these changes:

(1) PBS determinations will be compelled to reward 'innovation' at the expense of the fundamental goal of ensuring the affordability of therapeutically effective medicines for Australians.
(2) The new 'transparency' measures will favour the 'non-transparent' costing claims of the drug companies. US pharmaceutical companies will manipulate the review process in their quest to have their drugs subsidised. This will result in wastage of public funds in order to subsidise fictitious innovations costs.
(3) Patent extensions will significantly increase the financial burden on the PBS and delay the entry of generics in the Australian market.
(4) Australian drug prices will rise by a substantial amount.

We provide evidence to support the high probability of these outcomes below.

Scenario -- Step 1:

The fundamental goals of the PBS – assuring affordable, therapeutically effective medicines for Australians -- will be overturned in favour of rewarding 'innovation' in drug production.

Supporting evidence:

Article 1 of Annex 2-C enshrines the idea of acknowledging and rewarding 'innovation' by pharmaceutical companies as a top priority -- a priority over and above the provision of affordable medicines for all Australians. An explicit

[65] Under Chapter 17, Article 10.1.
[66] Under Chapter 17 Article 10.2 and 10.5
[67] 'The Generics Industry in 2005: A New Threat to Pharma': www.researchandmarkets.com/eports/851/851.htm
[68] ITR (2002), Discussion paper on patent extensions and springboarding, and the effect on generic pharmaceuticals manufacturers in Australia, Department of Industry, Tourism and Resources, Canberra. June 2002.

acknowledgment of the need to 'ensure equitable and affordable access to necessary medicines' for all Australians is absent from the Agreement.[69]

The Agreement also establishes a 'Medicines Working Group' to 'promote discussion and mutual understanding of issues relating to this Annex'[70]. Given the failure of the Annex to explicitly acknowledge the importance of equitable and affordable access to medicines, one must conclude that the Working Group will not be concerning itself with this issue.[71]

Scenario – Step 2:
Public funds will be wasted on subsidizing fictitious innovation costs.

This is because the new process targets only one small part of the decision making process – and the very end part at that. To ensure that the PBAC is subsidising the most cost effective new drugs, transparency would have to be built into the decision-making process *from the very beginning.* The first critical step would be to require pharmaceutical companies to provide the PBAC and the pricing authority with transparent information about costing and therapeutic advantages of new drugs, which would be equally open to public scrutiny.

Getting serious about transparency would therefore mean requiring pharmaceutical companies to provide the PBAC with transparent information about the pricing and therapeutic advantages of their drugs in the first place.

This is unlikely for at least two reasons:

(a) First, it would reveal that the Pharma companies' claim to exorbitant drug prices (allegedly due to their enormous R&D costs) is not substantiated.

(b) Second, the Pharma sector has the capacity, determination, and resources to resist the demand for transparency in its own claims regarding pricing and therapeutic advantages of new drugs.

Supporting evidence:
(a) The most reliable evidence shows that US drug prices typically *do not* reflect the costs of innovation. Rather, inflated drug prices reflect high marketing expenditures and what the market will bear:

- *Spending on R&D by USP Pharma companies is dwarfed by spending on marketing and administration.* The world's 15 largest drug companies (of which most are American) spend almost three times more on marketing and advertising (35.3% of revenue on average) than on innovation (12.9%), clearly demonstrating that the high cost of US drugs is due to efforts to sell the drug rather than to create it. A typical example is Merck's Canadian promotion of just one drug, Vioxx, in

[69] See Ken Harvey, Thomas A Faunce, Buddhi Lokuge and Peter Drahos (forthcoming) 'For Debate: Will the Australia-United States Free Trade Agreement undermine the Pharmaceutical Benefits Scheme?' Article commissioned by the *Medical Journal of Australia*, 2004.
[70] Annex 2-C, Article 1.3.
[71] Ken Harvey, 2004: 'Pharmaceutical benefits and free trade: trouble ahead for subsidised medicines in Australia?' *the Drawing Board: Australian Review of Public Affairs*, March 19.

2000. It spent over US$6.25 million, ran over 1000 pages of journal ads and distributed over 1 milllion samples to doctor's offices. The US Pharma industry employs over 600 lobbyists and spent over US$78 million to make its views about intellectual property rights heard by politicians; and in the 2000 American elections 'Citizens for Better Medicare, at its peak, was spending more than US$1 million a week on advertisements all of it paid for by PhRMA', the industry lobby. [72]

- *US Pharma companies already receive extensive subsidisation of R&D costs from their own government and major drugs have been developed with taxpayer-funded research.* Between 1965-1992, 15 of the 21 most important drugs developed were based on knowledge and techniques of federally funded research. In most cases, the research had gone beyond concept stage to the molecule level, which means that the most risk-intensive phase of R&D is borne by the public sector, the National Institutes of Health (NIH). Indeed, most of the R&D costs for seven of the bestselling drugs for cancer, AIDS, hypertension, depression, herpes and anaemia were funded by the NIH. [73]

- *Despite generous public subsidisation, Americans pay the highest prices in the world for their drugs, and the dramatically rising drug bill – which rose 71% per year from 1987 to 2001*[74]*-- absorbs a major part of the health budget.* Moreover, US Pharma companies will go to enormous lengths to protect their profit margins. For example, when the NIH in 1995 sought to include a 'reasonable pricing' clause in contractual agreements whereby a drug company agrees to market all drugs developed with tax-payer funded R&D at a reasonable price, the amendment was overturned as a result of pharma lobbying. More recently, PhRMA has been actively opposing the introduction of legislation similar to the PBS which would make drugs more affordable in the US:

- In 2000, PhRMA took the US state of Maine to court to block the introduction of legislation similar to the PBS. Such legislation would have ensured (in the words of Maine's Governor) that 'ordinary people [would] be able to get the drugs they need without necessarily having to face the terrible choice between the rent, the food, and the medicine.'[75] Similarly, 'PhRMA filed lawsuits to stop the state of Florida from introducing a law requiring drug manufacturers to provide discounts if they wanted their drugs to be included on a list of preferred drugs for recipients of Medicaid. Florida Governor Jeb Bush stated "protecting the large profit margins for multibillion-dollar pharmaceutical companies is not a priority. We are

[72] Joel Lexchin, 'Intellectual Property Rights and the Canadian Pharmaceutical Marketplace: Where do we go from here?' School of Health Policy and Management, York University, May 2003, p.23.
[73] 'Drug Companies and the NIH. How the pharmaceutical industry is reaping billions of of taxpayer-funded research and development', Compiled by the Office of Rep. Bernard Sanders.
[74] Joel Lexchin, 'Intellectual Property Rights and the Canadian Pharmaceutical Marketplace: Where do we go from here?' School of Health Policy and Management, York University, May 2003.
[75] Buddhima Lokuge, Thomas Alured Faunce and Richard Denniss, A Back Door to Higher Medicine Prices? Intellectual Property and the Australia-US Free Trade Agreement. The Australia Institute, November 2003. For a discussion of the PBS-style proposal in Maine see Barrington, C. J. (2002), 'Concannon and Maine's prescription drug rebate statute: A twenty-first century solution to the Medicaid crisis', *Whittier Law Review*, 23; Phelps, W. (2001), 'Maine's prescription drug plan: A look into the controversy', *Albany Law Review*, 64.

> more concerned about making sure our senior citizens have better access to affordable prescription drugs".[76]

But US governments are still fighting. Six New England states (Maine, New Hampshire, Vermont, Rhode Island, Massachusetts, Connecticut) recently formed The New England Consortium. These states, along with New York, meet regularly to 'try to come up with a joint plan to either form a purchasing cooperative or otherwise control pharmaceutical prices'.[77] For these states, the PBS remains the model to be emulated.

Clearly then the only way that transparency can be in the national interest in this context is to insist that a mutual obligation be placed on US pharmaceutical companies to provide full disclosure of costing and therapeutic advantage upon which the PBAC and the pricing authority (PBPA) can base their respective determinations**.**

The US federal government itself has tried and failed to get pharmaceutical companies to reveal the basis of their costing decisions. When the investigative arm of the US congress, the General Accounting Office (GAO), sought to force Pharma companies to reveal estimates of their research, development, marketing and distribution costs for individual products, US drug companies fought the GAO all the way to the Supreme Court, where GAO's request was finally rejected.

If the US congress is unable to get US pharmaceutical companies to reveal the basis of their costing decisions, the chances of the Australian government succeeding appear slim indeed.

Scenario -- Step 3:

Pharmaceutical companies will manipulate the review process in order to overturn PBAC determinations. Pharma compliance with the status quo will not be accepted.

Supporting evidence

(1) While the Australian government claims that the review process does not provide an avenue for overturning PBAC decisions, a recent Senate submission by leading Australian academic experts and former PBAC members pointed out that *if we do not provide an appeals process that satisfies US Pharma companies, we will face large financial sanctions:*

> Under the FTA, Australia has undertaken to "make available an independent review process" by which a manufacturer can challenge PBS listing decisions made by the key committee, the Pharmaceutical Benefits Pricing Authority. The government has

[76] Buddhima Lokuge, Thomas Alured Faunce and Richard Denniss, A Back Door to Higher Medicine Prices? Intellectual Property and the Australia-US Free Trade Agreement. The Australia Institute, November 2003..

[77] *Prescription Drug Pricing Pathfinder: Current Attempts to Control Drug Prices.* http://www.law.berkeley.edu/library/classes/alr/pathfinerexample2/CurrentAttempts.html This site provides a good overview of the range of measures being proposed to come to terms with inflated US drug prices.

> repeatedly promised that this would not be able to set aside or overturn PBAC decisions. However, the realities of the FTA are that Australia is likely to face very large sanctions under the dispute resolution and enforcement sections of the FTA if it does not provide an appeals process that the US and its drug makers find acceptable. Any process that does not have the power to reverse decisions, and which merely returns a submission to the committee for further consideration, will not represent any advance for the American side or the US companies. According to several statements from the industry and the American side, an appeals process without power is not what they think they have secured.[78]

(2) Moreover, logic dictates that there is little point in having a review process if the outcomes of the review have no meaning. It is naive to think that negative review findings will not be used by US Pharma companies to pursue a change in PBAC decisions. As one leading analyst of the industry has noted:

> In briefings on the FTA, the Department of Health and Aging (DoHA) has drawn a distinction between the review mechanism proposed in the FTA and a comprehensive appeals process; DoHA argues that the proposed review process will not be able to overturn a PBAC decision. This interpretation is unsupportable. If reviews cannot result in PBAC decisions being overturned then what is the point of them? It seems inevitable that reviews of negative PBAC decisions will allow the numerous lawyers, large budgets, and formidable public relations machines of US pharmaceutical companies to wear the PBAC down. The end result will be drugs listed at higher prices than the PBAC originally thought justified by the pharmacoeconomic evidence.[79]

Scenario -- Step 4

New IP clauses -- especially in the area of data protection -- delay the release of cheaper generic drugs, lead to wastage of funds on duplicative research, and push up pharmaceutical prices – all without any added health benefit to Australians.

While Pharma companies will benefit from the new IP clauses under the deal, Australians, including the domestic generics industry, will be the losers. Patent extensions will delay the release of generic drugs and put an additional burden on the PBS, with no therapeutic gain.

Supporting evidence:

Studies by a number of subject-matter experts support this conclusion. For example:

(i) Assessments of the therapeutic value of new drugs reveal that innovation seldom leads to therapeutic improvements.

- Only a tiny minority of drug 'innovations' are therapeutically significant. Over a 21 year period, the French drug bulletin, Prescrire, has found that by far the majority (1780 of 2693 drugs) were superfluous new products that added nothing to the clinical possibilities offered by already available

[78] Peter Drahos, Thomas Faunce, Martyn Goddard, and David Henry. 'The FTA and the PBS'. A submission to the Senate Select Committee on the US-Australia Free Trade Agreement. May 2004.
[79] Ken Harvey, 2004: 'Pharmaceutical benefits and free trade: trouble ahead for subsidised medicines in Australia?' *the Drawing Board: Australian Review of Public Affairs*, March 19.

products.[80] Other studies have concluded similarly. Of the 455 new patented drugs introduced into Canada from 1996 to 2000, just over 5% were major therapeutic improvements, 204 were line extensions (typically a new strength of an existing medication), and 226 represented little or no improvement over existing medicines. In short, the large majority of drugs are basically 'minor variations on existing medications' – for example, the additions to the statin group of drugs for lowering cholesterol.[81] 'Since most drugs offer little or no therapeutic advantage over existing remedies then it stands to reason that most of the money spent on R&D is going into products that will build market share not products that will necessarily result in significantly better health outcomes.'[82]

(ii) Assessments of the costs of patent extension and delays in generics production.

- Indirect costs associated with the practice of 'evergreening' stall the marketing of generic drugs. 'When the Canadian Coordinating Office for Health Technology Assessment was about to release a report saying that all of the different drugs in the statin group were equivalent, Bristol-Myers Squibb, makers of one of these drugs, objected to the release of the report and went to court to block its publication.' While the case was thrown out, the Canadian agency spent 13% of its annual budget defending itself.[83]

- From a recent Parliamentary Library Research Paper:
  The flexibility that governments may need to address public health issues may be eroded by some of the provisions in article 17.10: 'Measures related to certain regulated products'. *The article entrenches strong new protection for pharmaceutical test data so that generic producers would have to wait five years for access to the data. That could delay access to affordable medicines and make their production more costly.* In addition, patent holders could use the limits on how governments provide marketing approval and safety permits to block production of essential generic medicines during a health crisis (emphasis added).[84]

- From a Senate Submission by academic experts and former PBAC members:
  Measures extending the large originator companies' rights in data protection will, in many cases, force generics makers to repeat clinical studies that have already been conducted. It is unlikely that ethics committees would approve such studies: to put patients at risk to provide data that are already well known would contravene basic international standards of human research ethics (emphasis added).[85]

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[80] 'Drugs in 2001: a number of ruses unveiled'. *Prescrire International* 2002; 11:58-60.
[81] Joel Lexchin, 'Intellectual Property Rights and the Canadian Pharmaceutical Marketplace: Where do we go from here?' School of Health Policy and Management, York University, May 2003, p.15.
[82] ibid, p.22.
[83] ibid. p.23
[84] Intellectual Property Rights and the Australia-US Free Trade Agreement, Research Paper No.14 2003-04. David Richardson, Economics, Commerce and Industrial Relations Section, 31 May 2004.
[85] Peter Drahos, Thomas Faunce, Martyn Goddard, and David Henry. 'The FTA and the PBS'. A submission to the Senate Select Committee on the US-Australia Free Trade Agreement. May 2004.

- From a report by an American expert on international drug pricing:
  Kevin Outterson, law professor at the University of West Virginia and an expert on international drug pricing, predicts that Australian drug prices will rise by at least 30% within five years under the deal:

> Australia got nothing on the pharmaceutical deal … It's exclusively to the United States' benefit … Australia has lower prices and a more functional and complete system than anyone else and that's exactly why the drug companies want to shut it down, because it is such an outstanding model … The FTA is designed to gum up the works on a very efficient, thoughtful system, that many of us wish we could import into the US … I am troubled by US trade representatives utilising the FTA to attack it just when our own domestic states are beginning to evaluate it and possibly embrace it … [under the deal prices will rise about 30 per cent in five years] The real cost will become evident three to four to five years out and at that time it will be too late … The FTA will be firmly ensconced.[86]

- From a report by Australian analysts:
  A widely cited report by the Australia Institute predicts that patent extensions under the deal will cost the PBS at least an extra $1.2 billion:

> In order to highlight the cost of potential changes to IP provisions in the FTA on the PBS and Australian taxpayers, this study examined five medicines nearing the end of their 20-year patent terms. These five products account for a significant proportion of expenditures in the PBS. *The study estimates the impact on the PBS of a range of delays that would be likely to result from the changes to Australia's IP regime and examines the cumulative cost to Australia over the four years from 2006 –2009* … The central case estimate, which is likely to be conservative given the impact of IP changes in the US, is that *the additional cost of delaying the entry of generic competition for these five drugs alone would be more than $1.12 billion over four years. A more conservative estimate of an 18 month delay would lead to an additional cost to the PBS of $850 million and the upper estimate of a 30 month delay would result in additional costs to the PBS of $1.56 billion over four years.* (emphasis added). [87]

The same report also predicted that prices of non-subsidised drugs would rise under the deal:

> *If the FTA extends monopoly protection over pharmaceuticals by delaying the entry of generic medicines [which it does], the prices of OTC medicines will also be affected.* For example, Australia could expect significant reductions in the price of the top selling non-sedating antihistamine Claratyne (and as a flow on, all other comparable antihistamines) when it comes off-patent in Australia in June 2006. This common OTC medication currently faces no generic competition in Australia. However, if IP changes as part of the Australia-US FTA come into effect then such price reductions will be delayed. In the US, the patent on Loratadine (the active ingredient of Claratyne) expired in 2002. Soon after expiration cheaper generic versions appeared on the market – 40 per cent cheaper than the original brand Claratyne.[88]

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[86] Cited in the *Sydney Morning Herald*, 'Prescriptions may rise 30% under FTA: academic'. May 20, 2004.

[87] Buddhima Lokuge, Thomas Alured Faunce and Richard Denniss, A Back Door to Higher Medicine Prices? Intellectual Property and the Australia-US Free Trade Agreement. The Australia Institute, November 2003.

[88] Buddhima Lokuge, Thomas Alured Faunce and Richard Denniss, A Back Door to Higher Medicine Prices? Intellectual Property and the Australia-US Free Trade Agreement. The Australia Institute, November 2003.

- A Senate Submission by leading academic experts and former PBAC officials predict that the deal will cost the PBS an extra $1.5 billion, with no increase in the health benefits to Australians:

> The full effect of the FTA on the pharmaceutical market is … unlikely to be felt for about five years. By that time, however, *it is plausible that the gap between US and Australian drug prices could be cut in half.* We estimate, very conservatively, that *Australia's PBS will have to pay at least one third more for its drugs with the FTA than without it. If the likely FTA effects are applied to 2003 figures, the extra cost to of the PBS to the government last year would have been around $1.5 billion for the same drugs at the same levels of use and with no increase in the health benefit to Australian patients.* Similar pressures would be felt by other buyers of prescription pharmaceuticals, particularly hospitals (emphasis added).[89]

- A Productivity Commission Report in 2003 predicted that savings of between $1 billion and $2.4 billion per year could be wiped out under the deal:

> A report by the Productivity Commission in 2003 highlighted the crucial role that generic competition played in the success of the PBS reference pricing system … [saving] Australia between $1 and 2.4 billion dollars annually … Therefore IP measures that delay generics and weaken reference pricing will have a significant impact on the cost and sustainability of the PBS.[90]

The entire thrust by Pharma for a new PBS regime that would increase the listing rate of 'new' medicines must be set against an irrefutable fact – namely, that Australia is already one of the world's leading consumers of new ('innovative') medicine. In 2001, the market share of new medicines in Australia was over 29%, on a par with Canada, but well ahead of the major European countries (ranging from 22%-27%), the UK (16%), and Japan (14.8%) – and closest to the US (32%).[91]

Given that 'innovative' seldom means 'better' in terms of health benefits, given that 'transparency' is being demanded of the PBS but avoided by the Pharmaceutical sector, and given that the changes are geared to achieving these outcomes, not to preserving the widely admired goals and achievements of the PBS, we conclude that the FTA is patently at odds with the national interest.

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[89] Peter Drahos, Thomas Faunce, Martyn Goddard, and David Henry. 'The FTA and the PBS'. A submission to the Senate Select Committee on the US-Australia Free Trade Agreement. May 2004.

[90] Buddhima Lokuge, Thomas Alured Faunce and Richard Denniss, A Back Door to Higher Medicine Prices? Intellectual Property and the Australia-US Free Trade Agreement. The Australia Institute, November 2003.

[91] Data reported by the Association of the British Pharmaceutical Industry: www.abpi.org.uk/statistics/section.asp?sect=1