Dr Hilary Bambrick
Postdoctoral Fellow
National Centre for Epidemiology and Population Health
The Australian National University
Canberra ACT 0200 Australia

T: +61 2 6125 8595
F: +61 2 6125 0740
E: hilary.bambrick@anu.edu.au
www.anu.edu.au

Public Health Impacts of the Proposed Australia-United States Free Trade Agreement: Pharmaceuticals and Food Safety

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

30 April 2004

Hilary Bambrick
National Centre for Epidemiology and Population Health

Dorothy Broom
National Centre for Epidemiology and Population Health

Richard Denniss
The Australia Institute

Thomas Faunce
ANU Medical School and Faculty of Law

Public Health Impacts of the Proposed Australia-United States Free Trade Agreement: Pharmaceuticals and Food Safety

Executive Summary

In this submission, we demonstrate how public health in Australia could be adversely affected by the adoption of the proposed Australia-United States Free Trade Agreement (AUSFTA).

We focus on two key areas important to public health. Firstly, we examine the problems with linking Australia's Pharmaceutical Benefits Scheme (PBS) to trade under the AUSFTA. We use a scenario of a future dispute over listing of a new pharmaceutical to highlight the potential for direct US impact on Australia's capacity to provide good medicines at low cost. Secondly, we discuss the potential for the AUSFTA to lower Australia's food safety standards. We highlight problems with the interpretation of 'science-based' risk assessment and describe how the AUSFTA – and the WTO Agreement on Sanitary and Phytosanitary (SPS) Measures more generally – has the capacity to weaken Australian quarantine practices, by increasing the pressure to 'harmonise downwards' Australia's food safety and agricultural standards. We use the case of bovine spongiform encephalopathy (BSE) to illustrate the past effectiveness of Australia's cautious approach to risk assessment.

The Pharmaceutical Benefits Scheme

Despite Australian Government assurances that the cost of pharmaceuticals will not rise under the AUSFTA, mechanisms in the AUSFTA will lead to increases in the costs of essential medicines, and to diminished access to them.

US Trade Representative Bob Zoellick did not dispute recent statements in a US Senate hearing that the AUSFTA would facilitate Australian consumers bearing a greater proportion of research and development (R&D) costs for US pharmaceuticals. Zoellick specifically suggested this might be achieved through the AUSFTA's express support for drug 'innovation' and R&D, the activities of the new Medicines Working Group and a mechanism to review decisions not to list drugs on the Pharmaceutical Benefits Scheme (PBS). These developments signal a shift towards commercialism in the principles under which the PBS operates. After briefly summarising the history and purpose of the PBS, we discuss these mechanisms and their potential to erode the PBS.

Principles and purpose of the PBS

The PBS allows the Federal Government to set a 'Commonwealth Price' as the basis of a subsidy to assist the supply of 'listed' drugs from approved pharmacists on presentation of a prescription. At its inception in 1953, the 'life-saving' drugs recommended to the Minister by Pharmaceutical Benefits Advisory Committee (PBAC) for listing 'must be decided on medical grounds alone.'[1] A 1987 amendment expressly allowed the PBAC to evaluate the comparative effectiveness and cost of drugs proposed for listing. The justification was that the

[1] Minister Sir Earle Page, Second Reading Speech *National Health Act* 1953 (Cth).

Commonwealth Government did not believe 'the taxpayer should foot the bill for very expensive drugs that offer only minimal advantages over cheaper alternatives.'[2]

The US is obligated under its *Trade Promotion Authority Act (2000) US* to ensure its trade agreements facilitate 'affordable' access to 'essential' medicines under the Doha Declaration of the convention on Trade Related Intellectual Property Rights (TRIPS). Yet, in the quest to make the Australian public pay more for US drugs, and if the trend of other bilateral negotiations in which it has been involved is repeated, the US may threaten to use various strategies under the AUSFTA to erode drug affordability criteria and the basic principles of egalitarian health care that underpin Australia's PBS.

The new PBAC review mechanism

The current PBS review mechanism is through appeal to the Federal Court. In a recent appeal, pharmaceutical manufacturers failed in challenging the PBAC's decision not to recommend listing of the expensive drug Viagra, which offered no therapeutic advantage over existing treatments (*Pfizer v Birkett* in 2000).[3] It is inevitable that their perceptions of what is achievable through any new 'review' process for PBAC decisions will be coloured by this negative experience.

The AUSFTA provides means for drug companies to strongly influence which drugs may be listed on the PBS, including a new 'review' mechanism in Annex 2-C 2 (f) of the draft AUSFTA for drugs whose listing has not been recommended by the PBAC. It appears likely that this process will be developed by a Medicines Working Group, which has no guaranteed influential representation by Australian consumers or Australian owned generic drug manufacturers. To show the potential harmful effects of this new mechanism, we sketch a foreseeable future scenario.

Assume in five years time, that a new US drug with large R&D costs has been advertised by Internet links from sites popular with Australian patients (as allowed by Annex 2-C5). Side letters in the AUSFTA between Mark Vaile and Robert Zoellick allow the US drug manufacturers to consult extensively with members of the PBAC as a new drug is being considered for listing, to lobby the PBAC and be given information facilitating an application to the Commonwealth price setting body. Further assume that despite using these opportunities, the drug is nonetheless rejected for PBS listing because the PBAC considers its expense is not matched by a substantial improvement in efficacy or reduction in toxicity over existing listed pharmaceuticals or treatments.

The US now decides to threaten moving beyond any consultative process to a dispute resolution Panel. In this case the Panel is specially convened under the AUSFTA article 21.7, and will comprise three trade and intellectual property experts, chosen from a list of ten potential members. One expert panellist will be nominated by each party and one (the Chair) will be jointly agreed. This unelected body of three persons will have the power to interpret Australia's compliance with obligations in the AUSFTA related to its PBS. This is a significant threat to Australia's sovereignty in the public health area.

Faced with determining whether the outcome of the review mechanism actually fulfils AUSFTA obligations, the Panel turns to the four interpretive 'principles' set out at the

---

[2] Minister Humphries, Second Reading Speech, 1987 amendments to *National Health Act* 1953 (Cth).
[3] *Pfizer Pty Ltd v Birkett* [2000] FCA 303 20 March 2003.

beginning of Annex 2-C. These principles are heavily weighted towards the agenda of the US pharmaceutical industry, emphasizing 'innovation,' 'research and development' and 'transparent, expeditious and accountable procedures' as well as 'competitive markets.' The important Australian principles of 'affordability' and 'comparative efficacy' are, in contrast, downplayed in 2-C 1 (c) and (d) and will need to be emphasized. Even in the sections dealing specifically with medicines, the AUSFTA positions trade as the central goal, while public health is merely peripheral.

If Australia attempts to pass legislation that does not adequately comply with the AUSFTA, the US will initiate dispute proceedings. Another US strategy might be to threaten to use article 21.2 (c) which allows a damages claim where a 'benefit' the US could reasonably have expected to accrue under Chapter 17 (Intellectual Property Rights) 'is being nullified or impaired as a result of a measure that is not inconsistent with this Agreement'. So even a breach of the *spirit* of the AUSFTA may be sufficient for retaliatory measures.

The overall US threat is that if this dispute settlement Panel decides that Australia is in breach of its AUSFTA obligations or even the spirit of the agreement, then article 21.11 (2) permits a 'suspension of benefits' or 'cross-retaliation' in other trade areas such as beef, lamb, or manufacturing. In order to prevent this, the party found to be non-compliant can pay monetary compensation (article 21.11 (5). Ongoing failure to comply may permit the Panel to impose an 'annual monetary assessment' (article 21. 12 (2)).

Under the AUSFTA, PBAC decisions not to list 'innovative' US drugs will have to be made in the shadow of threatened US trade retaliation. This pressure will be difficult to resist. It is imperative, therefore, that even, despite our strong contrary advice, if the AUSFTA is approved, strong legislative and administrative protections be immediately put in place to insulate the PBAC from such US threats to dismantle the price-restricting effects of Australia's PBS. These could include amendments to the Therapeutic Goods Act, the National Health Act and the Patents Act to emphasise the unqualified importance of universal access to affordable medicines and the capacity to do experimental work for new pharmaceuticals without infringing existing patents.

Quarantine and Food Safety

Chapter Seven of the draft AUSFTA deals with Sanitary and Phytosanitary (SPS) Measures. It states that its purpose includes providing a forum for addressing bilateral SPS matters and resolving trade issues. It explicitly states that it is intended to expand trade opportunities.

This emphasis on expansion of trade 'to the greatest extent possible' (7-4) will come at some cost to human health and agriculture, despite the stated objective that these should be protected. The 'science-based' risk assessment that is emphasised in the AUSFTA (and in the WTO's SPS Agreement more generally) is problematic, and allows no room for managing uncertainty.

The AUSFTA recommits Australia to the WTO's SPS Agreement, and strengthens the position of the US if they consider Australia to be in breach of the Agreement. This has serious implications for Australia's ability to protect public health through import risk assessment and quarantine protocols.

'Science-based' risk assessment

In the past, Australia has used the precautionary principle in its import risk assessments and quarantine responses. In the absence of full scientific certainty of a risk, Australia has taken a cautious approach, which has served Australia very well in protecting public health and agriculture, including, for example, against bovine spongiform encephalopathy (BSE), which is now distributed globally.

Article 7.4 of the AUSFTA establishes a joint committee to promote the application of the WTO's SPS Agreement. Under the SPS Agreement, the precautionary principle in import risk assessment can only be used to restrict imports for a matter of months, during which time the importing country is expected to carry out a 'scientific' risk assessment that must address specific (i.e. known) risks, and in the case of agriculture, quantify the impact on industry and economy.

However, specific risks are rarely certain. For example, despite the theoretical (and in some cases established) risks involved in farming and consuming genetically modified (GM) produce, in the absence of specific known and quantifiable risks Australia will have to accept GM produce from the United States. The same would be true for irradiated foods. Irradiation reduces the nutritional value of foods, but the precise health risks remain unspecified. The Australian government will not be able to protect public health pre-emptively, but will have to wait until people get sick and scientific data have been collected before it can act. By that time, as with BSE elsewhere, the damage will already be done.

The precautionary principle is well accepted across scientific disciplines, as an appropriate metric to inform decision making when risks are uncertain. It is not accepted by the WTO as scientific, but is seen solely as a protectionist measure to safeguard domestic industry.

Harmonising downwards

Australia is under increasing pressure to 'harmonise' its food standards with the international guidelines developed by the Codex Alimentarius Commission. Although the Codex recommendations were intended to set *minimum* standards in food safety and were never meant to be a ceiling on the standards that any given country could set, they are increasingly used as such by the WTO (Silverglade and Heller 1997; Silverglade 1999).

As Australia's standards of food safety are frequently above the Codex recommendations, Australia is expected to lower its standards in the interests of trade liberalisation.

The AUSFTA increases the pressure for downwards harmonisation of food safety and agricultural standards by recommitting Australia to a flawed interpretation of what 'science-based' means. Australia will be expected to accept US imports where there is potential for risk but this risk cannot be quantified.

Even when a risk has been quantified, import restrictions may still be removed following pressure from trading partners. For example, modelling conducted by CSIRO (commissioned by the Australian pork industry) put the likelihood of an exotic disease outbreak at between 94 and 99 percent with new quarantine protocols that allow import of uncooked pork (ABC 2004).

Although quarantine may not be directly named in the AUSFTA, it is nevertheless vulnerable to being undermined by the WTO dispute settlement process. Australia has already been forced to accept imports that it was restricting on the basis of caution. The WTO Dispute Settlement Body ruled in 1999 that Australia had to accept imports of fresh and frozen salmon (USTR 2000). The import restrictions were deemed not to have been based on science in the absence of a quantitative risk assessment (Pauwelyn 1999). In 2003, sea-lice were found under the skin of salmon imported into Australia from Norway (Green 2003). Although not a threat to human health, sea-lice can kill salmon, and their presence poses a direct and serious threat to the lice-free status of the Australian industry (Green 2003).

This example illustrates that pressure from trading partners, the system of dispute settlement under the WTO, and flawed interpretation of the SPS Agreement forced Australia to compromise its quarantine regulations; the result was introduction of a real threat to an Australian industry. Despite the subsequent discovery of sea-lice in imported salmon and apparent justification of industry concerns, the salmon ruling has set a precedent for further challenges to Australian quarantine regulations.

The case of BSE

The BSE epidemic began in Britain in the 1980s as a result of feeding ruminant material to cattle. International trade liberalisation has ensured that BSE is now geographically extremely widespread. In December 2003, the United States reported its first confirmed case of BSE (AFFA 2003; AQIS 2003), while Australia is one of very few countries still free of BSE.

Australia was protected from the epidemic through good agricultural practice and caution in import risk assessment. Australia had already banned animal feed from Britain in 1966 (Animal Health Australia 2000) over concerns about the sheep disease scrapie, two decades before specific dangers (i.e. BSE and variant CJD) of feeding ruminant material to other ruminants were known. Under the SPS Agreement, and with the added weight from the AUSFTA, Australia today would not be able to take this precautionary action, and would be vulnerable to WTO-sanctioned retaliation by trading partners.

Under international standards, animals declared unfit for human consumption may be used in animal feed ‘provided there are adequate precautions to prevent misuse and to avoid dangers to human health and animal health’ (Codex Alimentarius Commission 1993, p.21). That is, animals that are not deemed fit for human consumption can still end up as part of the human food system. The failure to revise the standards suggests a failure to learn from mistakes.

Codex recommends that inspection should be cost-effective (Codex Alimentarius Commission 1993). If the risk for a particular disease or defect is low, then testing for it may not be cost-effective. These recommendations therefore place industry interests above those of public health.

In 2001, Australia banned the importation of beef products from 30 European countries after increased surveillance led to the identification of BSE affected animals (FSANZ 2001b) and the realisation that BSE was much more widespread than previously thought (FSANZ 2001a). Japan only detected its first case of BSE in 2001 when it introduced rigorous screening. That so many countries previously considered safe were reclassified as at risk for BSE highlights the importance of rigorous surveillance.

The testing regime in the United States has, in contrast, been described as extremely inadequate (The New York Times 2003), sampling only one in 1000 cattle slaughtered each year (Teather 2003), and most of these were staggering, disoriented or unable to walk ('downers') (New Scientist 2003).

The confirmed case of BSE in the United States may not be isolated. Under the inspection regimes of most countries, only samples of those animals that appear ill may be sent for laboratory testing. Test results from slaughtered 'at risk' animals are available only after the meat and meat products have departed the slaughterhouse. Before the confirmed case of BSE, some 20 000 'downers' were consumed each year in the United States (New Scientist 2003). The current United States testing regime does not prevent infected meat from entering the food chain (The New York Times 2003), but only allows products to be recalled. The particular cow in the United States found to have BSE was declared fit for human consumption nearly two weeks before the test results were available, and would not normally have been tested except for an unrelated injury (Teather 2003). Furthermore, two-thirds of the cattle that were imported from Canada with the infected cow could not be traced (United States Department of Agriculture 2004).

Since the BSE case, the United States is expected to increase its testing almost ten-fold, to between 200 000 an 300 000 cattle annually, or up to one percent. Ninety-nine out of every one hundred cattle would not be tested, even though the US is no longer BSE-free. The president of the US Meat Export Federation, Philip Seng, recently stated that Japan's call for the US to test all of its cattle was 'unscientific' (US Office of the Scientific Liaison 2004). Since its own BSE scare in 2001, Japan now tests every cow intended for human consumption.

The AUSFTA states that the regulatory systems and risk assessment processes of each party will be respected (7-4). Even after its first case of BSE, the US has vastly inadequate testing regimes in place. 'Respect' for the US's regulatory systems will be misplaced, and could be detrimental to the health of Australians and the integrity of Australia's agricultural industry. Australia will be expected to accept products that the United States considers safe, but which may fall short of current Australian standards. Should Australia accept imports containing bovine material from a BSE-affected country where 99% of cattle are not tested?

The risk that BSE posed was not known at the time that Australia invoked import bans on risky material, but its caution in restricting imports has since proven justified. Such theoretical risk and the use of the precautionary principle is not allowed under the SPS Agreement, and is not permitted under the AUSFTA.

Even now, international regulations may be too weak; much of the certification and regulation is based on industry self-regulation and report. The BSE incident should serve as a warning; a practice that is internationally accepted can still be dangerous.

Protecting public health from the AUSFTA

Both the PBS and quarantine are threatened by the AUSFTA. In order to protect Australia from the public health dangers of the AUSFTA and any future trade agreements, the Senate should consider the following principles:

1. The fundamental PBS principles of 'affordability' and 'comparative efficacy' that underpin Australia's egalitarian health care should be strengthened. Currently these are under-emphasised and under threat in the AUSFTA.

2. The PBAC should be protected from pressure from the pharmaceutical industry. If there is to be a Medicines Working Group, it must have guaranteed influential representation by Australian consumers and generic drug manufacturers.

3. Strong legislative and administrative protections must be immediately put in place to insulate the PBAC from US threats to degrade the affordability of pharmaceuticals under the PBS.

4. In the absence of absolute certainty, the precautionary principle is a valid, scientifically accepted approach to decision making. It should be enshrined in the AUSFTA and accepted by the WTO. The precautionary principle should be legitimate standard practice in risk assessment.

5. The AUSFTA threatens Australia's sovereignty over protecting the health of its population and its agricultural industry. Australia should be able to maintain its high standards of food safety.

6. Australia should not succumb to pressures to harmonise downwards its food and agriculture safety standards, but should instead be working to improve standards internationally.

7. Politics have no place in deciding quarantine policies.

8. Government has a responsibility to protect and promote the health of its people, regardless of short-term political considerations.

These eight principles must be upheld to ensure continued access to affordable, quality medicines and a safe food supply for all Australians.

References

ABC (2004) *Political backlash expected on import decision*. Last updated 20 February 2004, date accessed 15 March 2004. http://www.abc.net.au/rural/news/stories/s1049675.htm.

AFFA (2003) *Presumptive diagnosis of BSE in United States. Media Release.* Last updated 24 December 2003, date accessed 29 April 2004. http://www.affa.gov.au/ministers/truss/releases/03/03377wtj.html.

Animal Health Australia (2000) *Animal Health in Australia 2000*. http://www.aahc.com.au/status/ahiareport/2000/.

AQIS (2003) *Imported food inspection scheme notice: BSE case confirmed in the United States of America*. Last updated 31 December 2003, date accessed 29 April 2004. http://www.affa.gov.au/corporate_docs/publications/pdf/quarantine/border/ifn2003n40_03.pdf.

Codex Alimentarius Commission (1993) *Recommended International Code for the Ante-Mortem and Post-Mortem Inspection of Slaughter Animals and for Ante-Mortem and Post-Mortem Judgement of Slaughter Animals and Meat*, FAO & WHO. ftp://ftp.fao.org/codex/standard/en/CXP_041e.pdf.

FSANZ (2001a) *Australia announces new measures to protect public from the effects of BSE*. Last updated 18 July 2001, date accessed 31 January 2004. http://www.foodstandards.gov.au/mediareleasespublications/mediareleases2001/australiaannouncesne709.cfm.

FSANZ (2001b) *Certifying the BSE-free status of beef and beef products*. Last updated 5 Jan 2001, date accessed 2 Feb 2004. http://www.foodstandards.gov.au/mediareleasespublications/factsheets/factsheets2001/certifyingthebsefree697.cfm.

Green, B. (2003) *Seizure of infected salmon imports. Tasmanian Government media release*. Last updated 16 September 2003, date accessed 29 April 2004. http://members.iinet.net.au/~jenks/salmon7.html#BG1.

New Scientist (2003) *US bans consumption of crippled cows*. Last updated 31 Dec 2003, date accessed 15 March 2004. http://www.newscientist.com/hottopics/bse/bse.jsp?id=ns99994523.

Pauwelyn, J. (1999) The WTO Agreement on Sanitary and Phytosanitary (SPS) Measures, as applied in the first three SPS disputes: *EC - Hormones, Australia - salmon* and *Japan - varietals*. *Journal of International Economic Law* **2**(4): 641-664.

Silverglade, B. (1999) *The WTO Agreement on Sanitary and Phytosanitary Measures - Weakening Food Safety Regulation to Facilitate Trade?* (conference paper). Incorporating Science, Economics, Sociology and Politics in Sanitary and Phytosanitary Standards in International Trade, Irvine, California, 25 January.

Silverglade, B. and I. R. Heller (1997) *Re: Docket No. 97N-0218. Consideration of Codex Alimentarius Standards; Advanced Notice of Proposed Rulemaking.* Last updated 6 October 1997, date accessed 29 April 2004.
http://www.cspinet.org/reports/codex/proprule.htm.

Teather, D. (2003) 'Herds quarantined in US mad cow disease' *The Guardian***,** 27 December 2003.
http://www.guardian.co.uk/bse/article/0,2763,1112865,00.html.

The New York Times (2003) 'Warnings that went unheeded' *Sydney Morning Herald***,** 26-28 December 2003: 11.

United States Department of Agriculture (2004) *Transcript of Technical Briefing on BSE with Dr. Ron DeHaven, Chief Veterinary Officer and Dr. Steve Sundlof, Center for Veterinary Medicine, Food and Drug Administration -- Washington D.C. February 9, 2004*. Last updated 9 February 2004, date accessed 23 February 2004.
http://www.usda.gov/Newsroom/0073.04.html.

US Office of the Scientific Liaison (2004) *Testing of all cattle for BSE unscientific: U.S. exporter*. Last updated 12 March 2004, date accessed 15 March 2004.
http://osl.fass.org/thenews2.asp?news_id=245.

USTR (2000) *2000 National Trade Estimate Report on Foreign Trade Barriers*, United States Office of the Trade Representative.
http://www.ustr.gov/html/2000_contents.html.