

# Losing Our Health: The Australia-United States Free Trade Agreement

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## Introduction

The text of the Australia-United States Free Trade Agreement (AUSFTA) has recently been released. Public health policy is embodied within this *trade* agreement. The fundamental purpose of international trade agreements is to reduce barriers to trade. Barriers to trade in services are largely domestic regulations.

Australian health care policy, including that for pharmaceuticals, will be linked by the AUSFTA to the nation with arguably the most inefficient and inequitable health and pharmaceutical system of developed nations. Public health principles, equity and universality will not be priorities.

The impact is wide ranging. For instance, it may determine approval processes for pharmaceuticals; public health legislation on tobacco and alcohol control; qualifications for health professionals; licensing requirements or standards within health facilities; quantifying the number of service providers and facilities; and regulations on health insurance. Public health measures will become open to interpretation by trade dispute panels. Expansion of existing activities will be restrained. In the future, AUSFTA obligations will have to be taken into account when making health policy decisions.

## The Details

Sections in the text of the AUSFTA that are relevant to health care include:

- Chapter 10 Cross-Border Trade in Services;
- Chapter 13 Financial services (includes health insurance);
- Annex II (includes exclusions for Social services);
- side letter regarding gambling, alcohol, firearms and tobacco;
- Chapter 2: Market Access, Annex 2.C Pharmaceuticals;
- Chapter 17 Intellectual Property Rights;
- side letter on the Pharmaceutical Benefits Scheme (PBS).

### *Services, exclusions, qualifications and regulation*

Chapter 10 deals with trade in services. As the AUSFTA is a 'top down' agreement using a negative list approach, any service not explicitly excluded automatically comes under the terms of the agreement. This is in contrast to a 'bottom-up' agreement with a positive list of what is included. The issue of clearly defining exclusions is thus crucial.

The agreement uses the same contentious wording for the exemption of public or essential services as the World Trade Organisation (WTO) *General Agreement on Trade in Services (GATS) Article 1.3*. This states that the obligations do not apply to a 'service supplied in the exercise of governmental authority' if not supplied on a 'commercial basis, nor in competition with one or more service suppliers'. Clearly, this

is very open to interpretation. The recent report of the Senate Inquiry into the General Agreement on Trade in Services and the Proposed Australia-United States Free Trade Agreement highlighted concerns with interpretation of this article.<sup>1</sup> The WTO has previously stated:

39. The hospital sector in many countries, however, is made up of government- and privately-owned entities which both operate on a commercial basis, charging the patient or his insurance for the treatment provided. Supplementary subsidies may be granted for social, regional and similar policy purposes. *It seems unrealistic in such cases to argue for continued application of Article 1:3 and/or maintain that no competitive relationship exists between the two groups of suppliers or services. In scheduled sectors, this suggests that subsidies and any similar economic benefits conferred on one group would be subject to the national treatment obligation under Article XVII.* [italics added]<sup>2</sup>

General exceptions for services (*Chapter 22 General Provisions and Exceptions, Article 22.1 General Exceptions subparagraph 2.*) are also the same as in the GATS (*Article XIV*). The *side letter regarding gambling, alcohol, firearms and tobacco*, states that regulation of retail trade services for tobacco products, alcoholic beverages, or firearms will typically fall within the exceptions provided under subparagraphs (a), (b), and (c) (iii) of *Article XIV of the GATS*.

This includes measures that are 'necessary to protect public morals or to maintain public order' and 'necessary to protect human, animal or plant life or health' if not applied as a means of 'arbitrary or unjustifiable discrimination between countries where like conditions prevail; or a disguised restriction on trade in services'. The WTO has previously used a very narrow interpretation of what is deemed 'necessary' and interpreted that the measure must be the least trade restrictive possible to achieve its objective.

*Annex II* sets out the specific service sectors, sub-sectors or activities which may maintain existing, or adopt new or more restrictive, measures that do not conform with obligations. Health care is listed in the section on social services.

A crucial question is how will health care be defined. WTO classification places medical, dental, nursing, midwifery, physiotherapy and paramedical services not occurring in a hospital under professional services in 'Business Services' and not in 'Health Related and Social Services'.

The agreement also states that to be excluded the service has to be a 'social service established or maintained for a public purpose'. The US Trade Representative (USTR) has previ-

ously indicated a narrow interpretation that the *Annex II* exclusion only applies where services are both entirely government financed and publicly delivered.<sup>3,4</sup>

The complex web of public-private relationships in Australia's health sector could expose many areas of health care to AUSFTA trade obligations. Self-definition has not applied in trade dispute procedures.

Health insurance is classified under non-life insurance in Financial Services. There is no mention of an exclusion of health insurance in *Chapter 13 Financial services* or *Annexes III and IV* (which lists exempt non-conforming measures). It would appear that this places the health insurance sector under the full obligations of the agreement.

*Article 10.7: Domestic regulation 2.* deals with qualifications and standards including those in the health care sector. Professional qualifications and licensing, accreditation and licensing of facilities, financing and funding of services and overall administration are covered. Governments have to ensure that measures in these areas are not 'unnecessary barriers to trade' and 'not more burdensome than necessary to ensure the quality of the service'. Of concern, this applies to non-discriminatory measures.

#### *Pharmaceuticals*

The PBS is dealt with specifically in *Chapter 2: Market Access, Annex 2.C Pharmaceuticals* and the *side letter on the PBS* and patents on pharmaceuticals in *Chapter 17 Intellectual Property Rights Articles 9 Patents* and *10 Measures Related to Certain Regulated Products*.

The Agreed Principles of *Annex 2.C* uses the language of the pharmaceutical industry and concentrates on the importance of 'innovation' and 'research and development' and ominously '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'. There is no mention of equity or universal access to affordable medicines. This is in complete contrast to the objectives of the PBS - comprehensiveness, universality and responsible community cost.

The pharmaceutical industry has consistently used rewarding innovation and research and development (R&D) to defend US prices. This is despite the pharmaceutical industry having been the most profitable industry in the US for each of the past 10 years, the most generous campaign contributor in the world, spending twice as much on marketing as on R&D and the fact that most new drugs on the market are replacements for cheaper generic versions<sup>5-10</sup>

An OECD report found about three-quarters of the final pharmaceutical expenditures are publicly reimbursed in the vast majority of OECD countries.<sup>11</sup> A US study showed that taxpayer-funded scientists and foreign universities conducted 85% of the published research studies, tests and trials leading

to the discovery and development of five innovative drugs.<sup>12</sup> The pharmaceutical industry in the US is described as lightly taxed and heavily subsidised. In addition to receiving research subsidies, the pharmaceutical industry in the US has low tax levels due to tax credits making their effective tax rate about 40% less than the average for all other industries.<sup>13</sup>

The US pharmaceutical industry is the largest lobby group in the US.<sup>5</sup> In the 1999-2000 US election cycle, pharmaceutical corporations spent over US\$177 million on lobbying. President Bush received US\$14 million from the US pharmaceutical industry during his 2000 campaign.

Budget papers for 2003-2004 of the Pharmaceutical Research and Manufacturers of America (PhRMA), the powerful trade association representing US pharmaceutical manufacturers, reportedly included US\$17.5 million to fight price controls and protect patent rights in foreign countries and trade negotiations of which US\$1 million was 'to change the Canadian health care system'.

US Democrat Senator Richard J Durbin has said in the Senate "PhRMA, this lobby, has a death grip on Congress". Democrat Senator Charles E Schumer said drug industry made wonderful products but was becoming 'despised and hated' because of aggressive efforts to keep prices and profits high.<sup>14</sup>

Overall, the agreement entrenches US government involvement into Australian pharmaceutical policy and pharmaceutical industry input into the Pharmaceutical Benefits Advisory Committee (PBAC) approval process. The agreement sets out the establishment of a Medicines Working Group and an 'independent' review process of PBAC decisions. The structure of both the Medicines Working Group and the 'independent' review have not yet been determined. The Medicines Working Group will comprise government officials of both countries to promote discussion on the issues of the agreement 'including the importance of pharmaceutical research and development to continued improvement of healthcare outcomes'. It provides for continued dialogue between the US and Australia on emerging health care policy issues. Again the emphasis is on the pharmaceutical industry with no mention of universal access to affordable medicines. This 'discussion group' is with a country where 40 per cent of its citizens cannot afford access to necessary drugs and many go to Canada and Mexico to buy them.

Under the provisions of the agreement, pharmaceutical companies will be able to request review of negative decisions to list their product. The Australian negotiators insist the independent review is not an appeals process and will not be able to overturn PBAC decisions. This is a play on semantics. Although not having direct power, decisions will be influenced, otherwise why have the process? There will be greater pressure to approve more expensive drugs that may not give any significant advantage over drugs that are already available. A further appeals process had previously been rejected in the Tambling Review of the PBS.<sup>15</sup>

Analysis by The Australia Institute concludes that the changes to Australia's pharmaceutical patent laws in the agreement will result in delays to the arrival of generic medicines resulting in higher cost for the PBS. This will inevitably cost the taxpayer and the consumer.

Professor Peter Drahos, an Australian expert on intellectual property law from the Australian National University has also said that the stringent US patent standards in the agreement, which go far beyond the international norm, will benefit US companies at the expense of Australian bio-tech and generic companies and the wider community.<sup>16</sup> The overall deal pushes towards higher prices and costs. Pharmaceutical companies will have their profits increased from the pockets of ordinary Australians.

Australian government representatives and negotiators are keen to emphasise that much of the agreement in relation to pharmaceutical policy already occurs and reflects the 'status quo'. A big distinction, however, is that this has previously occurred under Australian guidelines with public health principles and the welfare of the Australian people at heart. Now it will be incorporated in a trade agreement with another nation where the aim is to reduce trade barriers. Pharmaceutical policy will be institutionalised in a trade agreement.

#### *Dispute Settlement*

Any dispute arising from the agreement may ultimately be determined by a dispute settlement panel of three, the chair selected from a group who 'have expertise or experience in law, international trade, or the resolution of disputes arising under international trade agreements'.

Except for disputes involving enforcement of labour laws and environmental laws there is no requirement for panelists to have expertise or experience relevant to the subject matter under dispute. Hearings do not have to be public and the panel may invite advice or accept written views of non government representatives as long as both sides agree. The decision does not have to be made public and cannot be appealed. The panel can order that a law be changed or compensation paid. (*Chapter 21 Section B: Dispute Settlement Proceedings*)

What is considered necessary to protect human life or health, whether a particular health service is a social service for a public purpose, whether health qualifications or regulations are more burdensome than necessary, whether tobacco control regulations are the least trade restrictive or whether Australia is keeping to the obligations under *Annex 2.C Pharmaceuticals* and the *side letter on the PBS* may be determined by an international trade panel whose priority is reducing trade barriers not public health.

#### **The Governments' Positions**

The US and Australian governments appear to have different takes on the agreement. In relation to pharmaceutical policy, the Bush administration's strategy has been to undermine drug price controls in other developed countries. President Bush's

recently passed Medicare bill includes provisions to scrutinise 'protectionist' programs in foreign countries and if necessary eliminate them through free trade negotiations. The bill specifically forbids the government to use its influence to negotiate lower drug prices in its own country.<sup>17</sup> This was a key goal in the lobbying of the pharmaceutical industry.

In contrast to what the Australian government has been saying there are those in the US who believe cost of medications in Australia will be affected. Mr Zoellick told a US Senate finance committee after the AUSFTA was released that the agreement was aimed at changing the 'distribution' of prices in Australia between generic and patented drugs.<sup>18</sup>

There is the conviction that 'pricing constraints' in other countries shift 'the burden for R&D' to the consumers in the US. US Republican Senator Kyl, who was part of the US negotiating team, said at the hearing a way to address this "is to get the other countries of the world to help bear part of the burden of the R&D". The AUSFTA is seen as a step in a campaign to raise global pharmaceutical prices.<sup>18</sup>

Senator Kyl stated that the final agreement was a "breakthrough" in respect to pharmaceuticals but only the beginning of negotiations over Australia's pharmaceuticals system. "... I know that there is much more work that needs to be done in further discussions with the Australians." Senator Graham stated that the agreement "has had the effect of injecting more marketplace in the Australian pharmaceutical distribution system".<sup>18</sup>

There have been concerns raised in the United States about this. House of Representatives Democrat Leader Nancy Pelosi and eight other Democrats wrote to President Bush earlier this year saying:

(g)iven that far too many Americans cannot afford access to life-saving or life-prolonging medicines, it is astounding that the United States may seek to impose those shortcomings not only on Australia today but on the rest of the world tomorrow.<sup>19</sup>

A letter to the USTR, Mr Robert Zoellick, written by Democrat Congresswoman Rosa DeLauro and signed by seventeen other members of Congress said:

(w)e are deeply opposed to the trade office being used by the US pharmaceutical industry to achieve its strategic objective of raising worldwide drug prices to the level now paid by US consumers.<sup>20</sup>

#### **Conclusion**

Pharmaceutical companies may be celebrating the release of the AUSFTA as a 'Triumph in the Text' at the recent AUSFTA conference in Canberra<sup>21</sup> and Medicines Australia dinner where John Howard was given a hero's welcome.<sup>22</sup> The ultimate consequence for health care in Australia is the undermining of public health principles in the interests of international trade. The Australian people are the losers. We have nothing to celebrate.

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