Doctors Reform Society

PO Box 992
Gosford NSW 2250
Tel 02 9264 9084
Fax 02 9267 4393
drs@drs.org.au
www.drs.org.au

Submission to the

Senate Committee

on

The Australia-United States Free Trade Agreement (AUSFTA)

May 2004

INTRODUCTION

The Doctors Reform Society (DRS) is an organisation of doctors formed in 1973 to support the introduction in Australia of universal health insurance, initially Medibank, now Medicare. The DRS continues to advocate for equitable universal access to quality health care for all members of Australian society according to need and not the ability to pay. The DRS welcomes this opportunity to contribute our views to this inquiry.

The DRS has previously addressed health implications of economic globalisation, the General Agreement on Trade in Services (GATS) of the World Trade Organisation (WTO) and the bilateral free trade agreement (FTA) between Australia and the United States (US) in submissions (2001-2003) to the Department of Foreign Affairs and Trade (DFAT) and to the Senate Inquiry on the General Agreement on Trade in Services and the proposed Australia-US Free Trade Agreement.

The fundamental purpose of international trade agreements is to reduce barriers to trade. Barriers to trade in services are largely domestic regulations. The DRS strongly believes health-related services should not be negotiated in trade agreements. The DRS believes the market ideology of trade agreements threatens universal health insurance schemes like Medicare, the Pharmaceutical Benefits Scheme and public health principles. In this submission, the DRS will address specific concerns in relation to health care issues and the Australia-United States Free Trade Agreement (AUSFTA).

The Doctors Reform Society is concerned that public health policy has been embodied within the AUSFTA. 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.[1-14] Public health principles, equity and universality will not be priorities.

The DRS believes benefits for Australia from the AUSFTA are doubtful and the potential cost to the community great. The predicted economic gains from an AUSFTA determined in the original study by the Centre for International Economics commissioned by the government were extremely modest, only 0.3 percent of GDP per year after 10 years and this was if all trade barriers were removed.[15] Other economic studies by ACIL consultants and the Productivity Commission predicted losses.[16,17] The gains in agriculture have been much less than predicted. There are doubts from several quarters on the projected gains predicted in the recent Centre for International Economics (CIE) analysis[18] of the AUSFTA including trade economists, intellectual property law experts and reports from DFAT.[19]

The United States has shifted to pursuing bilateral and regional rather than multi-lateral trade agreements as the provisions go far beyond what has been possible to negotiate in the WTO. For example, US bilateral and regional agreements have provided far stronger protection to US patent holders and investors than offered through the WTO.[20]

Professor John Quiggin, School of Economics and School of Political Science and International Studies at the University of Queensland, has stated that the terms of such 'integration' rather than 'free trade' agreements pursued by the US are those set by the more powerful party. An integration agreement involves the adoption of common economic policies on a wide range of issues, including intellectual property, public ownership of infrastructure and competition policy. This results in smaller less powerful nations integrating or adopting the economic and social institutions of the larger more powerful nation. An agreement with the US will inevitably result in Australia adopting American institutions and not *vice versa.*[21,22]

Three objectives of the US in the AUSFTA negotiations that are particularly relevant to pharmaceuticals and health care are to - *'address issues of anti-competitive business conduct, state monopolies, and state enterprises*'; *'reduce or eliminate artificial or trade-distorting barriers to US investment in Australia*'; and to *'have Australia apply levels of (patent) protection (for undisclosed test data and other information)…in line with US law*'.[23]

SUMMARY

The main concerns of the DRS in relation to health care are:

- Public services are not protected from the market thrust of the agreement;
- Health care is not unambiguously excluded and is thus open to market forces and US style corporatisation;
- Health professional qualifications, licensing and standards within health facilities are not to be *'unnecessary barriers to trade*' and are to be *'not more burdensome than necessary*';
- The US government and pharmaceutical companies will have greater influence over the functioning of the PBS thus compromising public health principles and the price control capacity of the Pharmaceutical Benefits Advisory Committee (PBAC);
- The introduction of an *'independent review process*' of negative PBAC decisions will lead to greater pressure on the PBAC to approve more expensive drugs even when they may not give any significant advantage over drugs that are already available;
- The creation of a *'Medicines Working Group*' (MWG) with the US government will be another mechanism for the US pharmaceutical industry through their government to continue to pressure the Australian government to make further changes to pharmaceutical policy that would lead to greater profits for the US industry;
- Increased patent rights for pharmaceutical companies will delay the entry of new generic drugs onto the market by the generic industry maintaining higher prices for longer and thus higher costs for the PBS and ultimately the Australian people;
- The beginning of direct-to-consumer advertising (DTCA) of pharmaceutical drugs by inclusion of a clause on internet DTCA. This opens up DTCA for further '*discussion*' and negotiation under trade priorities rather than public health merits. There will be opportunity for further pressure from pharmaceutical companies.
- What is considered necessary to protect human life or health; whether a particular health service is a social service for a public purpose; public health measures such as tobacco and alcohol control; and pharmaceutical policy – will all be open to interpretation by trade dispute panels whose priority is reducing trade barriers not public health.

Sections in the text of the Australia-US Free Trade Agreement (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).*

THE DETAILS

Exclusions and Impacts on Health Care:

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.

Chapter 10 Cross-Border Trade in Services, Article 10.1 Scope and Definition, replicates the contentious language used in the World Trade Organisation (WTO) *General Agreement on Trade in Services (GATS) Article 1.3* for exclusion of *'services supplied in the exercise of governmental authority'*:

> ARTICLE 10.1 : SCOPE AND COVERAGE
> 4. This Chapter does not apply to:
> (e) services supplied in the exercise of governmental authority within the territory of each respective Party.
> A **service supplied in the exercise of governmental authority** means any service which is supplied neither on a *commercial basis*, nor in *competition with* one or more service suppliers. (italics added)

This gives little assurance for public services including health care. 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.[24] 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 and bold added] [25]

General exceptions for services (*Chapter 22 General Provisions and Exceptions, Article 22.1 General Exceptions subparagraph 2.*) are the same as in *GATS Article XIV* which includes measures that are:

> a) *necessary* to protect public morals or to maintain public order;
> b) *necessary* to protect human, animal or plant life or health;
> c) *necessary* to secure compliance with laws or regulations which are not inconsistent with the provisions of this Agreement including those relating to:
> i) the prevention of deceptive and fraudulent practices or to deal with the effects of a default on services contracts;
> ii) the protection of the privacy of individuals in relation to the processing and dissemination of personal data and the protection of confidentiality of individual records and accounts;
> iii) safety; (italics added)

With the important proviso:

> … that such measures are not applied in a manner which would constitute a means of arbitrary or unjustifiable discrimination between countries where like conditions prevail; or a disguised restriction on trade in services

In the side letter regarding gambling, alcohol, firearms and tobacco, it is stated 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 *GATS Article XIV*.

Any dispute that may arise may be subject to scrutiny by a trade dispute panel. The WTO has previously used a very narrow interpretation of what is deemed *'necessary'*, typically as essential, and interpreted that the measure must be the least trade restrictive possible to achieve its objective.[26] This standard gives priority to free trade and restricts national measures to protect public health. In over 50 years of the General Agreement on Tariffs and Trade (GATT) with an identically worded exception clause (Article XXb), there has only been one recent case where a dispute panel has upheld an inconsistent measure on the basis of this exception.[27]

Annex II contains exclusions for social services including health care and states:

> Australia reserves the right to adopt or maintain any measure with respect to the provision of law enforcement and correctional services, and the following services *to the extent that they are social services established or maintained for a public purpose*: income security or insurance, social security or insurance, social welfare, public education, public training, health and child care. (italics added)

A crucial question is how will health care be defined. As the agreement uses a negative list approach, it is essential for clarity.

Although health care is not specifically stated as 'public', whether public or private it would have to be deemed a *'social service established or maintained for a public purpose'* to be excluded. A US definition of this can differ markedly from other interpretations. Market ideology which dominates the US health system interprets many areas of health care not as social services for a public purpose. Rather, individual responsibility and the relationship between the provider and consumer (patient) are paramount.

There have been differences between Canadian and US interpretations in relation to health care exclusions in the similarly worded North American Free Trade Agreement (NAFTA). The US Trade Representative has indicated a narrow interpretation that the Annex II exclusion only applies where services are both entirely government financed and publicly delivered.[28,29] The more the system is privatised, the less likely is the claim that all services are provided for a public purpose. 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.

The classification system for services that will be used is not stated. WTO classification places medical, dental, nursing, midwifery, physiotherapy and paramedical services not occurring in a hospital under professional services in *Business Services* and <u>not</u> in *Health Related and Social Services* as in the *UN Central Product Classification*. Health insurance is classified under non-life insurance in *Financial Services* which includes insurance, banking and other 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 in relation to Chapter 13). It appears that this places the health insurance sector under the full obligations of the agreement.

The Australian negotiators have not clarified these issues.

This all seems to lead to murky definitions open to interpretation by trade officials whose priority is reducing trade barriers not public health.

The market and deregulation thrust of the agreement applies to services that are not excluded seen in the following articles in *Chapter 10 Cross-Border Trade in Services*.

10.2 National Treatment:

> Each Party shall accord to service suppliers of the other Party treatment no less favourable than that it accords, in like circumstances, to its own service suppliers.

10.3 Most-Favoured-Nation:

> Each Party shall accord to service suppliers of the other Party treatment no less favourable than that it accords, in like circumstances, to service suppliers of a non-Party.

10.4 Market Access:

> A Party shall not adopt or maintain, either on the basis of a regional subdivision or on the basis of its entire territory, measures that:
> (a) impose limitations on:
> (i) the number of service suppliers whether in the form of numerical quotas, monopolies, exclusive service suppliers, or the requirement of an economic needs test;
> (ii) the total value of service transactions or assets in the form of numerical quotas or the requirement of an economic needs test;
> (iii) the total number of service operations or the total quantity of services output expressed in terms of designated numerical units in the form of quotas or the requirement of an economic needs test;1 or
> (iv) the total number of natural persons that may be employed in a particular service sector or that a service supplier may employ and who are necessary for, and directly related to, the supply of a specific service in the form of numerical quotas or the requirement of an economic needs test; or
> (b) restrict or require specific types of legal entity or joint venture through which a service supplier may supply a service.

and

10.5 Local Presence:

> A Party shall not require a service supplier of the other Party to establish or maintain a representative office or any form of enterprise, or to be resident, in its territory as a condition for the cross-border supply of a service.

Similarly, the following articles in *Chapter 13 Financial Services* apply to financial services that are not excluded.

13.2 National Treatment:

> 1. Each Party shall accord to investors of the other Party treatment no less favourable than that it accords to its own investors, in like circumstances, with respect to the establishment, acquisition, expansion, management, conduct, operation, and sale or other disposition of financial institutions and investments in financial institutions in its territory.
> 2. Each Party shall accord to financial institutions of the other Party and to investments of investors of the other Party in financial institutions treatment no less favourable than that it accords to its own financial institutions, and to investments of its own investors in financial institutions, in like circumstances, with respect to the establishment, acquisition, expansion, management, conduct, operation, and sale or other disposition of financial institutions and investments.

13.3 Most-Favoured-Nation:

> Each Party shall accord to investors of the other Party, financial institutions of the other Party, investments of investors in financial institutions, and cross-border financial service suppliers of the other Party treatment no less favourable than that it accords to the investors, financial institutions, investments of investors in financial institutions, and cross-border financial service suppliers of a non-Party, in like circumstances.

13.4 Market Access for Financial Institutions:

A Party shall not adopt or maintain, with respect to investors of the other Party, either on the basis of a regional subdivision or on the basis of its entire territory, measures that:
(a) impose limitations on
(i) the number of financial institutions whether in the form of numerical quotas, monopolies, exclusive service suppliers, or the requirement of an economic needs test;
(ii) the total value of financial service transactions or assets in the form of numerical quotas or the requirement of an economic needs test;
(iii) the total number of financial service operations or on the total quantity of financial services output expressed in terms of designated numerical units in the form of quotas or the requirement of an economic needs test;13-1 or
(iv) the total number of natural persons that may be employed in a particular financial service sector or that a financial institution may employ and who are necessary for, and directly related to, the supply of a specific financial service in the form of a numerical quota or the requirement of an economic needs test; or
(b) restrict or require specific types of legal entity or joint venture through which a financial institution may supply a service.

and

13.5 Cross-Border Trade:

1. Each Party shall permit, under terms and conditions that accord national treatment, crossborder financial service suppliers of the other Party to supply the services specified in Annex 13-A. National treatment requires that a Party shall accord to cross-border financial service suppliers of the other Party treatment no less favourable than that which it accords to its own financial service suppliers, in like circumstances, with respect to the supply of the relevant service.
2. Each Party shall permit persons located in its territory, and its nationals wherever located, to purchase financial services from cross-border financial service suppliers of the other Party located in the territory of the other Party. This obligation does not require a Party to permit such suppliers to do business or solicit in its territory. Each Party may define “doing business” and “solicitation” for purposes of this obligation, as long as such definitions are not inconsistent with paragraph 1.
3. Without prejudice to other means of prudential regulation of cross-border trade in financial services, a Party may require the registration of cross-border financial service suppliers of the other Party and of financial instruments.

Professional Qualifications and Standards:

Article 10.7: Domestic regulation 2. (a), (b) and (c) that apply to qualifications and standards in the health field is the same as *GATS Article VI Domestic Regulation 4. (a), (b) and (c)*:

4. With a view to ensuring that measures relating to qualification requirements and procedures, technical standards, and licensing requirements do not constitute unnecessary barriers to trade in services, each Party shall endeavour to ensure, as appropriate for individual sectors, that such measures are:
a) based on objective and transparent criteria, such as competence and the ability to supply the service;
b) ***not more burdensome than necessary*** to ensure the quality of the service; and
c) in the case of licensing procedures, not in themselves a restriction on the supply of the service. (italics and bold added)

This covers professional qualifications and licensing, and licensing and accreditation of facilities, financing and funding of services and overall administration. Of concern, this applies to non-discriminatory measures.

The Pharmaceutical Benefits Scheme:

The Pharmaceutical Benefits Scheme (PBS) is dealt with specifically in *Chapter 2: Market Access, Annex 2.C Pharmaceuticals* and the *side letter on the PBS*.

- ***Principles***

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 term 'innovation' is value laden. In Australia, the issue has been whether the innovation is of value in terms of an additional benefit for the patient. It is not innovation per se that is wanted - it is better care for patients. A US report from the National Institute for Health Care Management found that relatively few of the new drugs approved during the period examined in the study, 1989 to 2000, were highly innovative, and that modified versions of older medications (the so-called 'me-too' drugs) had become increasingly dominant over time.[30]

The pharmaceutical industry has consistently used rewarding innovation and research and development (R&D) to defend high 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.[30-37]

An OECD report found about three-quarters of the final pharmaceutical expenditures are publicly reimbursed in the vast majority of OECD countries.[35] 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.[38] 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.[39]

The US pharmaceutical industry is the largest lobby group in the US.[40] 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.[41]

- ***Pharmaceutical industry input and review process***

Both *Annex 2.C* and the *side letter on the PBS* incorporate Pharmaceutical industry input into the Pharmaceutical Benefits Advisory Committee (PBAC) approval process both before and after a decision has been made. The side letter states that before approval companies are provided with:

> 1. (a) an opportunity to consult relevant officials prior to submission of an application for listing, including on the selection of a comparator pharmaceutical;
> (b) an opportunity to respond fully to reports or evaluations relating to the applications that are prepared for the technical subcommittees of the Pharmaceutical Benefits Advisory Committee (PBAC);
> (c) an opportunity for a hearing before PBAC while it is considering reports or advice from the technical subcommittees to the PBAC regarding applications; and
> (d) sufficient information on the reasons for its determination on an application, on an expeditious basis, to facilitate any application to the Pharmaceutical Benefits Pricing Authority.

If not happy with a negative decision, pharmaceutical companies are given a further review process:

> 2. Australia shall provide an opportunity for independent review of PBAC determinations, where an application has not resulted in a PBAC recommendation to list. (side letter on the PBS)
>
> 2. (f) make available an independent review process that may be invoked at the request of an applicant directly affected by a recommendation or determination. (Chapter 2: Market Access, Annex 2.C Pharmaceuticals)

The structure of the '*independent*' review has not yet been determined. 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 what is the purpose of the process? Introducing a review process must imply that decisions will be 'reviewed' and thus there is the possibility that some will, as a result, be modified. As this applies only to negative decisions there will be an upward shift to costs. 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.[42]

Once listed, further opportunity for drug prices to keep rising is assured due to the statement in the *side letter on the PBS*:

> 4. Australia shall provide opportunities to apply for an adjustment to a reimbursement amount.

Although the Australian negotiators say this provision already exists and will not change things, it is now embodied in the trade agreement and thus under the obligations and possible dispute procedures of the AUSFTA. Significantly there are no provisions to review prices downwards.

- ***Medicines Working Group***

In *Chapter 2: Market Access, Annex 2.C Pharmaceuticals* there is a proviso to establish a Medicines Working Group (MWG) to promote discussion *'including the importance of pharmaceutical research and development to continued improvement of healthcare outcomes'*. It is to *'comprise officials from federal government agencies responsible for federal healthcare programs and other appropriate federal government officials'*.

The Medicines Working Group will provide for continued dialogue between the United States 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 is unbalanced and based on commercial principles. 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. There is no accountability to the Australian people or parliament.

What has Australia to gain from US government pharmaceutical policy? Australia's excellent pharmaceutical system that other nations attempt to emulate is recognised worldwide. In this agreement, however, it will be Australia integrating the US system and not vice versa.

In a testimony to the US Senate Finance Committee on Pharmaceuticals, Gerard Anderson of Johns Hopkins University has said that it is not surprising that the US pays considerably more for pharmaceuticals, as the US has no national strategy for determining appropriate utilisation, comparing prices to what other countries pay, setting a reasonable research and development level or reasonable profit level. As the US has done little, he believes it unfair to ask other countries to dismantle their programs which are effectively controlling pharmaceutical prices and promoting appropriate utilisation.[13]

The Bush administration's strategy in relation to pharmaceutical policy 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.[4043,44] That provision was a key goal in the lobbying of the pharmaceutical industry.

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, told a US Senate finance committee after the AUSFTA was released that 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*".[45]

The evidence does not support this or that raising prices in other countries would lead to lower prices in the US.[46-49] For example, audited financial reports of major pharmaceutical companies in the UK, showed that all research costs were paid, with substantial profits left over, based solely on domestic sales at British prices.[50] A Canadian report found rising R&D expenditures of 79 research pharmaceutical companies in Canada were all paid for by domestic sales at Canadian prices.[51] In Australia, innovative products are priced closer to the average of the price in comparison countries, suggesting that the PBS approach to pricing rewards advances in treatment.[52]

Considering the relative population size, GDP and health spending in the US to other nations, it would be expected that the US would invest more in R&D.[46,53] According to industry figures 62% of sales of new medicines marketed since 1997 are generated on the US market compared with 21% on the European market. Yet research spending was only 1.4 times higher in the US compared to Europe in 2002 and the US produced 43% of new chemical and biological entities from 1998 to 2002 compared with 38% for Europe.[54] The UK, Switzerland, Sweden, Belgium and Denmark are some European countries that spend more of their GDP on R&D for new drugs than the US.[51]

In his address, Senator Kyl continued that the final agreement was a "*breakthrough*" in respect to pharmaceuticals but only the beginning of negotiations "*… I know that there is*

much more work that needs to be done in further discussions with the Australians." Senator Graham stated at the hearing that the agreement "*has had the effect of injecting more marketplace in the Australian pharmaceutical distribution system*".[45]

There have been concerns raised in the United States. House of Representatives Democrat Leader Nancy Pelosi and eight other Democrats wrote to President Bush earlier this year after reading the text of the agreement 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.[55]

A letter to the US Trade Representative (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.[56]

Tom Allen, Democrat, US House of Representatives said at completion of negotiations:

> While these changes are less than what the US pharmaceutical manufacturers wanted, they are more than Australian and American consumers deserve.
> ….. Since American consumers have both the least leverage and the highest drug prices in the world, Australian consumers should be concerned.[57]

All this amounts to the US government and pharmaceutical companies having an influence in the workings of the PBS. 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' and changes are minor. Discussions and opportunities for comment already occur during the approval process and a company can re-submit its case if rejected.

A big distinction, however, is that this has 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. The PBS is open to further discussion and negotiation and possible dispute resolution in a trade tribunal. Pharmaceutical policy will be institutionalised in a trade agreement.

Pharmaceutical Patents:

Chapter 17 Intellectual Property Rights Articles 9 Patents and *10 Measures Related to Certain Regulated Products* are relevant to patents on pharmaceuticals. 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 includes extensions of patent periods in some circumstances and changes that make it easier for drug companies to raise legal objections and delay the production of generic drugs. In the US, drug companies have used such legal tactics aggressively. Since the PBS price control system relies on comparisons with cheaper generic drugs, delays in the production of generic drugs will contribute to price rises. All of 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 that go far beyond the international norm will benefit US companies at the expense of Australian bio-tech and generic companies and the wider community.[58]

Off-patent drugs sold under generic brand names are cheaper than brand name drugs under patent. The availability of generic drugs presents considerable competition and is a force for lower prices. Delaying generic companies access to pharmaceutical patent information or impeding their capacity to prepare for generic production, would cost Australians more by delaying the onset of lower prices.[59] An earlier report by The Australia Institute estimated that the additional cost to Australians of delaying the entry of generic competition for five selected drugs would be more than $1.12 billion over four years.[60]

The USTR 2004 Special 301 Report shows the US push on increasing intellectual property rights (IPR) and says that the FTA with Australia strengthens these rights and is TRIPS plus:

> The United States is committed to a policy of promoting increased intellectual property protection. In this regard, we are making progress in advancing the protection of these rights through a variety of mechanisms, including through the negotiation of free trade agreements (FTAs). We are pleased that the recently concluded FTAs with Central America including the Dominican Republic, Morocco and Australia will strengthen the protection of IPR in those countries. Specifically, the intellectual property chapters of these agreements provide for higher levels of intellectual property protection in a number of areas covered by the TRIPS Agreement.[61]

Canada became party to a FTA with the US in 1987 and subsequently Mexico joined in the North America Free Trade Agreement (NAFTA) in 1994. The pharmaceutical industry has had intimate involvement in shaping the trade agreements that Canada has been involved in. Significant changes to Canada's pharmaceutical policy have resulted with the main beneficiary being the pharmaceutical industry. For example, the cost of a prescription in Canada has risen dramatically as a result of the long delay that is now required before generic equivalents appear on the market. Since Canada entered into trade agreements their balance of trade in pharmaceuticals has plummeted and imports now make up over 75% of the value of their pharmaceutical market. Although investment in research and development increased after their FTA with the US, in the past few years it has slowed down relative to sales.[62]

Direct-to-consumer advertising:

Direct-to-consumer advertising (DTCA), is mentioned in *Chapter 2: Market Access, Annex 2.C Pharmaceuticals 5. Dissemination of Information*. DTCA by pharmaceutical companies of approved pharmaceuticals will be allowed on the internet as long as it is *'truthful and not misleading' and 'includes a balance of risks and benefits'*. The negotiators state that this again reflects the 'status quo' as it states *'as is permitted under each Party's laws, regulations and procedures'* and there is no intention of changing the laws. There is no satisfactory answer as to why it is mentioned in the agreement and whether this could result in DTCA being 'discussed' in the MWG and further negotiations where further pressure will come to bear. This could be the first step to more widespread DTCA.

At present DTCA is only allowed in the US and New Zealand. The pharmaceutical industry claims that DTCA informs patients and improves health care. It has been reported, however, that advertisements can often confuse and mislead patients and inappropriately

raise prescription rates.[63-67] In the US the greatest increases in retail sales and number of prescriptions has been by far for the most heavily advertised drugs.[68] A study on prescribing in primary care found that more advertising leads to more requests for advertised medicines and more prescriptions.[69]

A Canadian parliamentary report on prescription drugs concluded that DTCA contributes to increased health care costs, does not provide balanced and unbiased information, is potentially harmful to consumers and has no ongoing scrutiny.[70] Another Canadian report on the impacts of DTCA found a negative effect on treatment appropriateness and no evidence of improved drug utilization, improved doctor/patient relations, or reductions in hospitalization rates, serious morbidity or mortality attributable to DTCA.[71] A report on DTCA of pharmaceuticals in NZ by a group including all the professors of general practice in NZ concluded that there is convincing evidence to justify a ban of DTCA of prescription-only medicines in NZ.[72] In Australia, the *Galbally Review of Drugs, Poisons and Controlled Substances Legislation* recommended against DTCA.[73]

Dispute Process:

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 decision does not have to be made public and cannot be appealed. The panel can order that a law be changed or compensation paid. If there is non-compliance with a ruling, cross-retaliation (suspension of 'benefits of equivalent effect') in the form of trade sanctions can result.

(*Chapter 21 Section B: Dispute Settlement Proceedings*). *Article 21.8: Rules of Procedure 1. (d)* and *3.* appears to provide a token gesture to other perspectives. The article states the panel may invite advice or accept written views of non government representatives as long as both sides agree:

> 1. (d) that the panel shall consider requests from non governmental persons or entities in the Parties' territories to provide written views regarding the dispute that may assist the panel in evaluating the submissions and arguments of the Parties and provide the Parties an opportunity to respond to such submissions and arguments;
>
> 3. On request of a Party, or on its own initiative, the panel may seek information and technical advice from any person or body that it deems appropriate, provided that the Parties so agree and subject to such terms and conditions as the Parties may agree.

This is open to the panel to decide and rather than public health or social advocate groups the concern is that this could be an avenue for further industry pressure.[74]

The central criterion for resolving trade disputes is the promotion of free trade, not the protection of public health. International legal scholars have frequently and consistently noted the trade bias of the WTO in cross-border disputes relating to the environmental consequences of trade and it has been stated that the same is likely to apply to disputes where trade may have consequences for public health.[75] Trade and investment tribunals have consistently given trade rules liberal reading, extending their application to policies and laws that one might have reasonably assumed to be beyond their reach.[76] These

dispute panels can override decisions of national courts and are not accountable to the Australian parliament or public.

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.

Cost to the Community:

The overall deal pushes towards higher prices and costs. Pharmaceutical companies will have their profits increased from the pockets of ordinary Australians.

Representatives of the Department of Health and Ageing have conceded that they could not guarantee that the cost to the PBS would not rise as a result of the AUSFTA (Department of Health and Ageing AUSFTA briefing, Canberra, March 8 2004).

Dr Maurice Rickard in a Research Note for the Social Policy Group, Australian Parliamentary Library, has said there would be significant disadvantages for Australia's system of pharmaceutical supply if changes to the PBS sought by the US such as to PBS pricing controls or delaying access to patents were made.[59]

The potential cost effects resulting from the pharmaceutical impacts of the AUSFTA were not taken into account in the Centre for International Economics (CIE) report. The section on pharmaceuticals appeared very superficial. Many issues were brushed over. It basically summed up that they were not sure what is going to happen but if something does happen it will be minimal, so the impact on pharmaceuticals was excluded from the quantitative analysis. In the first part of the section it was stated that one of the reasons for rising costs in the PBS has been aggressive marketing by the pharmaceutical industry. This was, however, disregarded in their assessment of any impacts.[18] More detailed analysis of potential costs showing a very different picture has been carried out.[77]

There will also be the cost of disputes and litigation that will inevitably result. The threat or potential for litigation may also have negative repercussions by stifling policy development. Such threats of possible litigation can have a dampening effect on enactment of environmental or public health measures.[76,78]

A cost to the Australian community of the AUSFTA will be the loss of autonomy in domestic social policy and the uptake of US social institutions. Social policies such as those related to health care will be determined by a trade agreement.

CONCLUSION

Public health is a notable area of concern with the Australia-US FTA. For the reasons discussed above, the DRS believes the potential costs to the community from the AUSFTA vastly outweigh the potential benefits. We do not support the agreement in its current form.

REFERENCES

1. Anderson G, Poullier J. Health spending, access, and outcomes: Trends in industrialized countries. *Health Affairs* 1999;18:34-41.
2. Anderson J, Hussey P. Comparing Health System Performance in OECD Countries. *Health Affairs* 2001;20:219-232.
3. Anderson GF, Reinhardt UE, Hussey PS, Petrosyan V. It's the prices, stupid: Why the United States is so different from other countries. *Health Affairs* 2003;22:89-105.
4. Blendon RJ, Schoen C, DesRoches CM, Osborn R, Scoles KL, Zapert K. Inequities In Health Care: A Five-Country Survey. *Health Affairs* 2002;21:182-191.
5. Budetti J, Duchon L, Schoen C, Shikles J. Can't Afford to Get Sick: A reality for millions of working Americans. New York: The Commonwealth Fund, 1999.
6. Davis K, Cooper BS. American Health Care: Why So Costly? Testimony for the Senate Appropriations Subcommittee Hearing on Health Care Access and Affordability: Cost Containment Strategies. New York: The Commonwealth Fund, 2003.
7. Davis K, Schoen C, Schoenbaum SC, Audet A-MJ, Doty MM, Tenney K. Mirror, Mirror on the Wall: Looking at the Quality of American Health Care Through the Patient's Lens. New York: The Commonwealth Fund, 2004.
8. Iglehart JK. The American Health Care System- Expenditures. *New England Journal of Medicine* 1999;340:70-76.
9. Pollock A, Rice DP. Monitoring health care in the United States - a challenging task. *Public Health Reports* 1997;112:108-114.
10. Reinhardt UE, Hussey PS, Anderson GF. US Health Care Spending In An International Context. *Health Aff* 2004;23:10-25.
11. Wagstaff A, van Doorslaer E, van der Burg H, Calonge S, Christiansen T, Citoni G, Gerdtham U-G, Gerfin M, Gross L, Hakinnen U. Equity in the finance of health care: some further international comparisons. *Journal of Health Economics* 1999;18:263-290.
12. Woolhandler S, Woodlander D. Cost of care and administration at for profit and other hospitals in the United States. *New England Journal of Medicine* 1997;336.
13. Anderson G. Testimony to the US Senate Finance Committee on Pharmaceuticals: Bloomberg School of Public Health, School of Medicine Johns Hopkins University, 2004.
14. Sager A, Socolar D. Prescription Drug Spending is Already Enough to Buy All the Drugs Americans Need Cutting Drug Prices and Expanding Coverage—Federal and State Efforts, Health Equity and Public Hospitals Caucus, American Public Health Association. Boston, 2000.
15. CIE. Economic Impacts of an Australia-United States Free Trade Area, prepared for the Department of Foreign Affairs and Trade. Canberra: Centre for International Economics (CIE), 2001.
16. Australian APEC Study Centre. An Australia-US Free Trade Agreement: Issues and implications. Canberra, 2001.
17. ACIL Consultants. A Bridge too Far? Canberra, 2001.
18. CIE. Economic analysis of AUSFTA Impact of the bilateral free trade agreement with the United States prepared for the Department of Foreign Affairs and Trade. Canberra: Centre for International Economics (CIE), 2004.
19. Wallace C. US trade deal won't have 'big effect' on investment. The Australian, 11 May 2004.
20. Kevin Watkins (Oxfam). Trade hypocrisy: the problem with Robert Zoellick. London: openDemocracy, 2002.
21. Quiggin J. Free Trade and Economic Integration with the United States: A Critical View. *Academy of the Social Sciences, Dialogue* 2003;22.
22. Quiggin J. Economic Evaluation of the Proposed Free Trade Agreement between Australia and the United States: School of Economics and School of Political Science and International Studies University of Queensland, Submission to Parliament of Australia, Joint Committee on Treaties Inquiry into the proposed Free Trade Agreement between Australia and the United States, 2004.
23. Zoellick RB. Letter to Senator Robert C. Byrd US Senate on Australia-US FTA. Washington, DC, 2002.
24. Report of the Senate Foreign Affairs Defence and Trade References Committee. Voting on trade: The General Agreement on Trade in Services and an Australia-US Free Trade Agreement. Canberra: Commonwealth of Australia, 2003.
25. WTO. Health and Social Services Background Note by the Secretariat. Geneva: Council for Trade in Services, World Trade Organisation (WTO), S/C/W/50, 18 September 1998, 1998.
26. Lipson DJ. Negotiating Health Services in Trade and Integration Agreements in the Americas. Washington, DC: Public Policy and Health Program, Pan American Health Organization, World Health Organization (PAHO/WHO), 2002.
27. Sanger M. Reckless Abandon: Canada, the GATS and the Future of Health Care. Ottawa: Canadian centre for Policy Alternatives, 2001.
28. Labonte R. Economic Globalization, Trade Liberalization, Governance and Health. Ottawa: Canadian Society for International Health (CSIH), http://www.csih.org/who/Tradehealth_e.htm, 2000.

29. Flood C. NAFTA: Have we traded away our capacity for innovative health reform? In: K C, ed. Trading Away Health? Globalization and Health Policy Report from the 14th Annual Health Policy Conference of the Centre for Health Services and Policy Research. Vancouver, 2001.
30. NIHCM. Changing Patterns of Pharmaceutical Innovation. Washington, DC: National Institute for Health Care Management, 2002.
31. Baker D, Chatani N. Promoting Good Ideas on Drugs: Are Patents the Best Way? The Relative Efficiency of Patent and Public Support for Bio-Medical Research: Center for Economic and Policy Research, 2002.
32. Global 500. Top performing companies and industries, top companies: highest profits: Fortune Magazine, http://www.fortune.com/lists/6500/g500_topperf-co-highprofit.html, 2002.
33. Inouye B. Unpacking the Pharma Biotech Engines: How the leading pharmaceutical corporations are driving the biotech agenda. Ottawa: Polaris Institute, 2002.
34. Mahan D. Profiting from Pain: Where Prescription Drug Dollars Go. Washington DC: Families USA Foundation, 2002.
35. Jacobzone S. Pharmaceutical Policies In OECD Countries: Reconciling Social And Industrial Goals (Labour Market and Social Policy Occasional Paper No. 40). Paris: Organisation for Economic Co-operation and Development (OECD), 2000.
36. NIH. NIH Contribution to Pharmaceutical Development. Bethesda, Maryland: Administrative Document, National Institutes of Health (NIH), 2000.
37. Pear R. Drug Companies Increase Spending to Lobby Congress and Governments The New York Times, 1 June, 2003.
38. NIH. NIH Contribution to Pharmaceutical Development, Administrative Document. Bethesda, Maryland: National Institutes of Health (NIH), February, 2000.
39. Young B, Surrusco M. RX R&D Myths: The Case Against the Drug Industry's 'R&D Scare Card'. Washington DC: Congress Watch, Public Citizen, 2001.
40. Baker BK. PhRMA's Relentless Drive for Profits Explains US Trade Negotiations. Health GAP, 10 December, 2002.
41. Pear R. Drug Companies Increase Spending to Lobby Congress and Governments. The New York Times, 1 June, 2003.
42. Senator Tambling Review Committee. Final Report of the Review of PBS Listing Arrangements. Canberra: Commonwealth of Australia, 2000.
43. Solomon N, Erlich R. Target Iraq: What the News Media Didn't tell You. Context Books, 2003.
44. The Medicare Prescription Drug Improvement and Modernization Act (US). 2003.
45. Senator Charles Grassly (Chair), USTR Robert Zoellick (Witness). The Administration's International Trade Agenda. Washington DC: Hearing of the Senate Finance Committee, United States Government, 2004.
46. Light DW, Lexchin J. Will Lower Drug Prices Jeopardize Drug Research? A Policy Fact Sheet. *The American Journal of Bioethics* 2004;4:3-6.
47. Mahan D. Out-of-Bounds: Rising Prescription Drug Prices for Seniors. Washington DC: Families USA Foundation, 2003.
48. Sager A, Socolar D. Lower US Prescription Drug Prices Are Vital to Both Patients and Drug Makers - But instead, U.S. Prices Have Been Rising Rapidly Relative to Those in Other Wealthy Nations. Boston: Health Reform Program, Boston University School of Public Health, 2003.
49. Socolar D, Sager A. Pharmaceutical Marketing and Research Spending: The Evidence Does Not Support PhRMA's Claims Update on Medicare and Prescription Drug Issues for the New Millennium, American Public Health Association Annual Meeting. Atlanta, Georgia, 2001.
50. Pharmaceutical Price Regulation Scheme (UK). Sixth Report to Parliament. London: Pharmaceutical Price Regulation Scheme, Department
of Health, 2002.
51. Patented Medicine Prices Review Board. A Comparison of Pharmaceutical Research and Development Spending. Ottawa: Patented Medicine Prices Review Board, Canada, 2002.
52. Productivity Commission. International Pharmaceutical Price Differences. Canberra: Productivity Commission, 2001.
53. Socolar D, Sager A. Pharmaceutical Marketing and Research Spending: The Evidence Does Not Support PhRMA's Claims. Update on Medicare and Prescription Drug Issues for the New Millennium, American Public Health Association Annual Meeting. Atlanta, 2001.
54. EFPIA. The Pharmaceutical Industry in Figures: Key Data, 2003 update. Brussels: European Federation of Pharmaceutical Industries and Associations (EFPIA), 2003.
55. Pelosi N, Hoyer S, Rangel C, Stark P, Matsui R, Levin S, Miller G, Spratt J, Clyburn J. Letter to President Bush on the Australia-US Free Trade Agreement. Washington DC: Congress of the United States, House of Representatives, 2004.
56. Fickling D. War on cheap drugs The Guardian, Tuesday January 20, 2004.

57. Tom Allen Democrat US House of Representatives. An American opinion on the Free Trade Agreement. Washington DC: Statement on completion of negotiations between the US and Australia to establish a free trade agreement, 10th February 2004.
58. Long S. Australian bio-tech and drug industry could be hit by FTA: AM, ABC Online, Friday, 5 March, 2004.
59. Rickard M. Free Trade Negotiations, the PBS, and Pharmaceutical Prices. Canberra: Research Note no. 32 2003-04, Social Policy Group, Parliamentary Library, Commonwealth of Australia, 2004.
60. Lokuge B, Faunce TA, Denniss R. A backdoor to higher medicine prices? Intellectual property and the Australia-US Free Trade Agreement. Canberra: The Australia Institute, 2003.
61. Office of the United States Trade Representative. 2004 Special 301 Report. Washington DC: United States Trade Representative (USTR), 2004.
62. Lexchin J. Globalization, trade deals and drugs: Heads the industry wins, tails Canada loses. Ottawa: Canadian Centre for Policy Alternatives Briefing Paper Series: Trade and Investment Vol 2, No 8, 2001.
63. Aikin KJ. Direct-to-Consumer Advertising of Prescription Drugs: Physician Survey Preliminary Results, 13 January, 2003.
64. Mintzes B. Letter to US Congressman Henry Waxman re Direct-to-Consumer Prescription Drug Advertisements. Vancouver: Centre for Health Services and Policy Research, University of British Columbia, 2002.
65. Wilkes M. Letter to US Congressman Henry Waxman re Direct-to-Consumer Prescription Drug Advertisements. Sacromento: University of California, Davis School of Medicine, 2002.
66. Waxman H. Expert Evaluation of Direct-to-Consumer Prescription Drug Advertisements: Minority Staff, Government Reform Committee, U.S. House of Representatives, 2002.
67. Woloshin S, Schwartz LM, Tremmel J, Welch HG. Direct-to-consumer advertisements for prescription drugs: what are Americans being sold? *The Lancet* 2001;358:1141-1146.
68. NIHCM. Prescription Drugs and Mass Media Advertising, 2000. Washington, DC: National Institute for Health Care Management, Research and Educational Foundation, 2001.
69. Mintzes B, Barer ML, Kravitz RL, Bassett K, Lexchin J, Kazanjian A, Evans RG, Pan R, Marion SA. How does direct-to-consumer advertising (DTCA) affect prescribing? A survey in primary care environments with and without legal DTCA. *CMAJ* 2003;169:405-412.
70. Bonnie Brown MP Chair. Opening the Medicine Cabinet: First Report on Health Aspects of Prescription Drugs: Report of the Standing Committee on Health, House of Commons Canada, 2004.
71. Mintzes B, Barer ML, Kazanjian A, Bassett K, Evans RG, Morgan S. An Assessment of the Health System Impacts of Direct-to-Consumer Advertising of Prescription Medicines (DTCA). Vancouver: Centre for Health Services and Policy Research, University of British Columbia, 2002.
72. Toop L, Richards D, Dowell T, Tilyard M, Fraser T, Arroll B. Direct to Consumer Advertising of Prescription Drugs in New Zealand: For Health or For Profit?: Report to the Minister of Health supporting the case for a ban on DTCA, New Zealand Departments of General Practice Christchurch, Dunedin, Wellington and Auckland Schools of Medicine, 2003.
73. Galbally R. Review of Drugs, Poisons and Controlled Substances Legislation Final Report: A Council of Australian Governments Review, Therapeutic Goods Administration, 2001.
74. Shaffer G. The World Trade Organization under Challenge: Democracy and the Law and Politics of the WTO's Treatment of Trade and Environment Matters. *Harvard Environmental Law Review* 2001;25:67-70.
75. Taylor L. External Liberalization, Economic Performance and Distribution in Latin America and Elsewhere. Helsinki: UNU/WIDER Working Papers No. 215, 2000.
76. Shrybman S. International trade agreements. In: Cardiff K, ed. Trading Away Health? Globalization and Health Policy, Report from the 14th Annual Health Policy Conference of the Centre for Health Services and Policy Research. Vancouver, 2001.
77. Drahos P, Faunce T, Goddard M, Henry D. The FTA and the PBS: Submission to the Senate Select Committee on the US Australia Free Trade Agreement, 2004.
78. Mann H. Private rights, public problems: A guide to NAFTA's controversial chapter on investor rights. Winnipeg: International Institute for Sustainable Development (IISD) and World Wildlife Fund (WWF), 2001.