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Trading in Our Health System?

The impact of the Australia-US Free Trade Agreement on the Pharmaceutical Benefits Scheme

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Summary

The Australian Government is currently negotiating a free trade agreement (FTA) with the USA. The objective is to reduce the barriers to trade between the two countries. The US Trade Representative has publicly stated that Australia's Pharmaceutical Benefits Scheme (PBS) is considered to be a barrier to trade.

The PBS was established in 1948 in response to concerns that not all citizens could afford expensive new medicines such as penicillin. All Australian citizens are covered by the system which subsidises the cost of most essential pharmaceuticals by fixing and capping patients' out of pocket expenses.

Important elements of the PBS include the manner in which drugs are chosen for inclusion in the scheme and the prices paid by the Commonwealth Government to the pharmaceutical companies. The selection and pricing process relies heavily on a cost-effectiveness analysis which ensures that the price paid for a new drug is determined primarily by the therapeutic benefits that flow from its use. According to one international expert, Professor Richard Laing of the Boston University School of Public Health, the PBS is the best in the world.

> Australia… is the one country which seems to have got it right, that what you want to do in controlling costs is to pay what the drugs are therapeutically worth. And the Pharmaceutical Benefits Scheme does that (Laing 2001).

The success of the PBS in controlling the prices paid by the Australian Government for pharmaceuticals has, however, resulted in concerns being expressed by pharmaceutical manufacturers. PhRMA, the pharmaceutical industry lobby group in the US, listed its misgivings with respect to the PBS in a submission to the US Trade Representative. These include the fact that applicants must:

- demonstrate significant clinical advantages and satisfactory cost-effectiveness compared to alternative drugs. The Pharmaceutical Benefit Pricing Authority (PBPA) uses such comparator pricing as leverage in negotiations with the applicant; and

- justify the listing and price of an innovative drug through economic and therapeutic studies that show a clinical advantage over its main comparator (PhRMA 2003).

While this evidence-based approach to price negotiations is central to the effectiveness of the PBS it is considered to be a barrier to trade by the US. The US Trade Representative's list of foreign barriers to US exports states that:

> Research-based US pharmaceutical firms are disadvantaged by several Australian Government policies. These include a reference pricing system that ties the price of innovative US medicine to the lowest priced medicine in the same therapeutic or chemical group, regardless of patent status of the medicines (USTR 2003, p. 12).

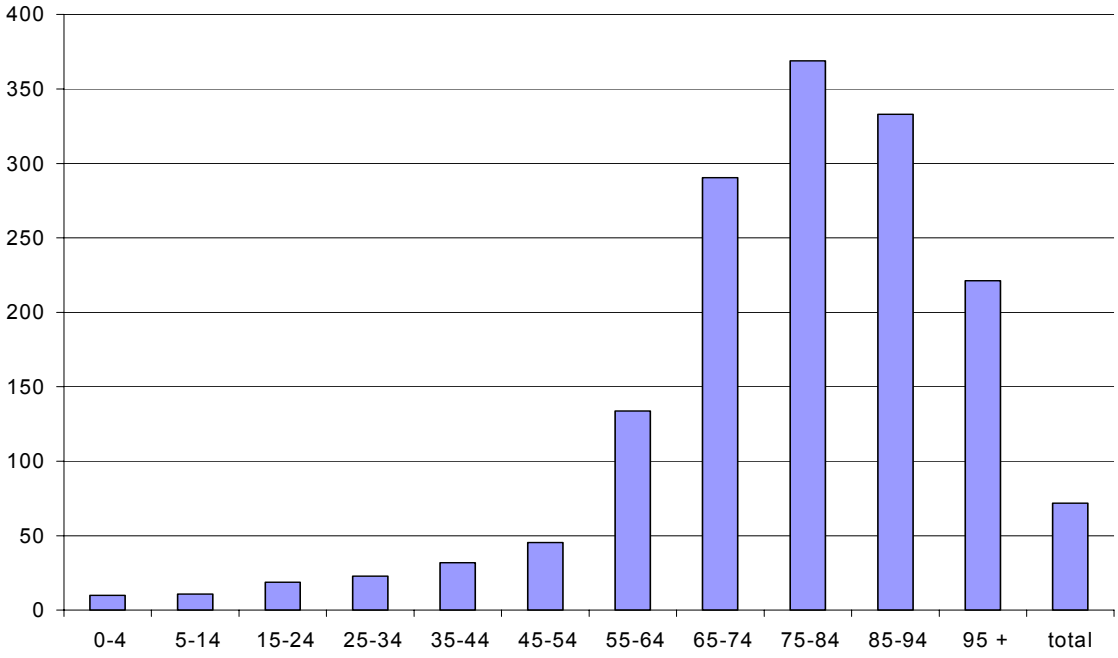
The pharmaceutical industry has publicly stated that the PBS serves to reduce the total amount paid for pharmaceutical products in Australia by around $1 billion (Evans 2002; Wallace 2003). However, analysis based on the findings of the Productivity Commission (2001) suggests that the impact of current price controls could be as much as $2.4 billion per year.

Increases in the cost of pharmaceuticals can be met in a number of ways, including:

- tax increases;
- reductions in other government services; or
- higher co-payments on concession card holders, non-concession card holders or both.

While the final distribution of these costs is a matter of government policy, there is no doubt that either taxpayers or users of the Australian health system will bear the final cost of any concessions to the pharmaceutical manufacturers made as part of an FTA with the US. As shown in Figure S1, it is the elderly who rely most heavily on the PBS.

Figure S1 Average PBS cost per person by age



Currently, concession card holders (including aged pensioners, people of pensionable age earning less than $50,000 per year, and recipients of a wide range of forms of government income assistance) pay $3.70 over the counter for each prescription for a drug listed on the PBS. Others pay $23.10. If drug prices were to rise by $1 billion and the additional cost fell wholly on non-concession card holders, the price of a prescription would need to rise 180 per cent to over $64 per script. Alternatively, if the

Government sought to share the increase in costs evenly between concession card holders and non-concession card holders, then non-concession card holders would face an 89 per cent increase in the cost of a co-payment while concession card holders would be required to pay more than $7.50 per script, a rise of more than 100 percent in the up-front cost of essential prescription drugs.

On the other hand, if the cost of concessions made during the FTA meant a $2.4 billion rise in the national drug bill, the cost to consumers would be much higher. If all of the costs were borne by non-concession card holders, then their co-payment would need to rise by more than 430 per cent. If the costs were shared evenly between concession card holders and non-concession card holders, then the price of a prescription paid by concession card holders would need to rise from $3.70 to $12.90. These figures are summarised in Tables S1 and S2.

Table S1 Impact of a $1 billion increase in the cost of pharmaceuticals to consumers

Payment type	Non-concessional		Concessional	
	Co-payment	Increase	Co-payment	Increase
Current co-payment	$23.10		$3.70	
100% borne by non-concession card holders	$64.59	180%	$3.70	0%
50% borne by non-concession card holders	$43.84	90%	$7.53	104%

Table S2 Impact of a $2.4 billion increase in the cost of pharmaceuticals to consumers

Payment type	Non-concessional		Concessional	
	Co-payment	Increase	Co-payment	Increase
Current co-payment	$23.10		$3.70	
100% borne by non-concession card holders	$122.66	431%	$3.70	0%
50% borne by non-concession card holders	$72.88	216%	$12.90	249%

The numbers presented above demonstrate the order of magnitude of the costs of implementing the changes sought by the pharmaceutical manufacturers through the FTA negotiations. If the Government wishes to insulate health consumers from such a rise in the cost of co-payments then the only alternative is to increase general tax revenue or reduce government expenditure on other essential services. Therefore, if the price of pharmaceuticals were to rise by $2.4 billion and the Commonwealth decided to absorb half the increase through the budget and pass half on to the sick, then the cost of co-payments for concession card holders would still need to rise by 125 per cent.

Pharmaceutical manufacturers have also signalled that Australia's restrictions on the advertising of medicines directly to consumers are another target of US-Australia FTA negotiations. If Australia were to deregulate this important mechanism that protects patients from opportunistic advertising the consequences would be two-fold. First, it would be likely to lead to a surge in direct-to-consumer advertising aimed at inducing patient demand for more expensive (but not necessarily therapeutically superior) brand-named medicines.

Secondly, it would lead to the substitution of pharmaceutical approaches for more appropriate lifestyle therapies in the treatment of illnesses such as obesity and smoking. If pharmaceutical advertisements were as successful in increasing demand as they have been in the US, the additional cost to the PBS would hundreds of millions of dollars per annum.

The only winners from implementing the changes to the PBS sought by the US negotiators will be pharmaceutical manufacturers. The costs of pharmaceuticals will rise, especially for the elderly in Australia, and the costs to the Commonwealth Government are also likely to rise. By design, the PBS combines the buying power of the government with extensive cost-effectiveness analysis to ensure that Australians pay the lowest reasonable price for their pharmaceuticals. Drug companies are not compelled to sell their products to Australians under the PBS; they choose to because it is profitable to do so.

The Howard Government has repeatedly claimed that signing an FTA with the US will be economically beneficial for Australia. While debate concerning the likely economic benefits of an FTA continues, with some commentators claiming they will be small or even negative, there has been virtually no debate on the distribution of any likely costs and benefits.

Finally, it is important to note that US pharmaceutical companies do not want the PBS abolished completely. Rather, they want the elements of the PBS that impose constrains on the prices of pharmaceuticals and the ability to advertise directly to consumers removed. If these changes occur, the cost of pharmaceuticals in Australia will rise substantially. These higher costs will be disproportionately borne by the sick and the elderly in Australia. Before signing any FTA, the Australian Government must be convinced that not only are there net benefits to Australia but that the distribution of the costs and benefits will be fair.

1. Introduction

1.1 The Australia-US Free Trade Agreement

Australia and the US are currently attempting to negotiate a free trade agreement (FTA) the objective of which is to reduce the barriers to trade between the two countries. Negotiations began in March 2003 and are expected to proceed for approximately 12 months.

The US has listed publicly those trade barriers which are of greatest concern to its negotiators. These concerns are listed in Zoellick (2002) and also found in the Office of the US Trade Representative's annual report on foreign trade barriers (USTR 2003). They include:

- Australia's use of quarantine restrictions to restrict trade;
- use of export monopolies to market Australian wheat, barley, sugar and rice;
- the labelling of genetically modified (GM) food; and
- restrictions on direct foreign investment in Australia (Zoellick 2002).

The US Government has also raised concerns about the effectiveness of the Pharmaceutical Benefits Scheme (PBS) in reducing the prices paid by Australians for pharmaceuticals. The US Trade Representative's list of foreign barriers to US exports states that:

> Research-based US pharmaceutical firms are disadvantaged by several Australian Government policies. These include a reference pricing system that ties the price of innovative US medicine to the lowest priced medicine in the same therapeutic or chemical group, regardless of patent status of the medicines (USTR 2003, p. 12).

This attitude mirrors the concerns expressed by the US pharmaceutical companies. PhRMA, the pharmaceutical industry lobby group in the US, listed its misgivings with respect to the PBS in a submission to the US Trade Representative. These concerns include that:

- applicants must demonstrate significant clinical advantages over the main comparator and satisfactory cost-effectiveness versus that comparator in order to achieve a premium price. The Pharmaceutical Benefit Pricing Authority (PBPA) uses such comparator pricing as leverage in negotiations with the applicant.
- applicants must justify the listing and price of an innovative drug through economic and therapeutic studies that show a clinical advantage over its main comparator (PhRMA 2003).

That is, the US pharmaceutical industry is concerned that, in order to charge the Australian Government a high price for a new drug, they actually have to provide

evidence that the new drug has demonstrable benefits. As discussed below, while this evidence-based approach to price negotiations is central to the operation of the PBS, it is considered to be a barrier to trade by the US.

The Australian Government has also made its objectives for the FTA explicit (Vaile 2003). While the Australian Trade Minister, Mark Vaile, provides a long list, many of which are general rather than specific, the first four are:

- the elimination of tariffs and other barriers to trade between Australia and the United States on the broadest possible basis;
- the removal of tariff rate quota restrictions on Australian exports to the United States, including those affecting exports of beef, dairy products, sugar, peanuts and cotton;
- the elimination or reduction of United States agricultural subsidies that affect Australian exports to the United States or to third country markets, as well as agreement for the United States not to subsidise exports of agricultural products to Australia; and
- a commitment to work together in the WTO negotiations towards achieving substantial improvements in market access globally, eliminating all export subsidies on agricultural products, and substantial reduction in domestic support for agriculture (Vaile 2003).

The stated objective of the Australian Government is to achieve as broad an agreement as possible (DFAT 2003a). However, improved access to the US market for Australian agricultural exports is a high priority.

Economic analysis commissioned by DFAT suggested net economic benefits to Australia from the proposed FTA in the order of $4 billion per year or 0.5 per cent of GDP (Berkelmans *et al*. 2002). Compared to the gains anticipated by the designers of National Competition Policy and the GST, a gain of around 0.5 per cent of GDP is relatively small. Further modelling by ACIL Consulting, however, suggests that the estimate by Berkelmans *et al.* (2002) was overstated. ACIL (2003) argued that the net benefits to Australia were likely to be significantly less than $4 billion.

DFAT has commissioned further research that indicates that the benefits to Australia of the FTA are broader than the economic benefits alone (APEC Study Centre 2002). While APEC Study Centre (2002) suggests that Australia's broader trade and strategic interests will be enhanced through an FTA with the US, others have judged that Australia's relationships with other key trading partners will be harmed in the process. An FTA between Australia and the US could have an adverse impact on other bilateral relationships or broader multilateral trade structures such as the General Agreement on Trade in Services (GATS) (ACIL 2003).

In addition, the successful negotiation of an FTA between Australia and the US could come at a cost to some groups in Australia as well as to the natural environment. The Australian Government has stated that it:

> will ensure outcomes from the FTA negotiations do not impair Australia's ability to deliver fundamental objectives in health care, education, consumer protection and supporting Australian culture and identity. The Government remains committed to preserving its ability to regulate in relation to social and cultural objectives, and will ensure the FTA is consistent with that goal (Vaile 2003).

Others are concerned about the willingness of the Australian Government to agree to changes in the way health and education services are delivered (see for example Ranald and Southalan 2003). In regard to the Australian health system, doubts have been fuelled by statements by both the representatives of the US pharmaceutical companies (Medicines Australia 2002), and the Office of the US Trade Representative (USTR 2003).

US pharmaceutical companies are particularly concerned with the operation of the PBS due to its effectiveness in lowering the prices paid by Australians for pharmaceuticals (PhARMA 2003; Productivity Commission 2001). The PBS, which is discussed in detail below, provides the Australian Government with a considerable amount of bargaining power as it acts largely as a monopsonist (sole buyer) of pharmaceuticals in Australia. The Australian Government combines its buying power with a heavy reliance on expert advice as to the benefits and value of new pharmaceuticals to minimise the cost of those pharmaceuticals to the Australian public (PhRMA 2003).

In order to reduce the effectiveness of the PBS, and in turn increase their profits, US pharmaceutical manufacturers have lobbied the US Government to ensure that Australia's PBS is included in the FTA negotiations. As discussed below, reforms to the PBS advocated by the US pharmaceutical industry include the elimination of the existing fixed 'co-payment' scheme and its replacement with a variable co-payment system (Medicines Australia 2002). At present, Australians face a fixed co-payment which limits the out-of-pocket expense of pharmaceuticals.

While concerns exist already over the current level of the pharmaceutical co-payment (Goddard *et al*. 2001), it is seen by the pharmaceutical companies as an obstacle to increasing revenues. The group representing pharmaceutical manufacturers in Australia, Medicines Australia, has said the need to protect the disadvantaged 'should not override the need to ensure that consumers take greater financial responsibility for their health' (Medicines Australia 2002, p. 12).

The political influence of the pharmaceutical industry with the current US Administration, as well as its publicly stated opposition to price control mechanisms inherent in the PBS, make the PBS a target for US trade negotiators. On the first day of public hearings into the FTA in the United States, drug industry lobbyist Joe Damond formally made the PBS a target for US interests, arguing that companies should be allowed to charge higher prices for medicines in Australia (Allard 2003).

Similarly, when questioned on this issue by the Pharmacy Guild of Australia in the past the Minister for Trade, Mark Vaile, refused categorically to exclude the PBS from FTA negotiations, stating:

> it is difficult to see why the PBS should be raised in any future negotiations on a free trade agreement with Australia, although that possibility cannot be ruled out entirely (quoted in PGA 2001, p.3).

Similarly, Labor MP Craig Emerson asked Foreign Minister Alexander Downer in Parliament to rule out placing the abolition of the PBS on the agenda of an FTA with the US. Minister Downer replied that if the US were to put forward proposals for the inclusion of the PBS then 'obviously that would be part of the negotiating process' (Hansard 2002, p. 9080).

Although both the Australian Government and the US negotiators have implied that the PBS is no longer on the bargaining table for FTA negotiators (see Davis 2003; Cole 2003), a closer examination of their statements suggests that this is not the case (Wallace 2003). The following sections outline the nature of the Australian PBS system and explore the implications of moving away from a highly regulated approach to the distribution of pharmaceuticals in Australia towards a deregulated approach such as the existing US system.

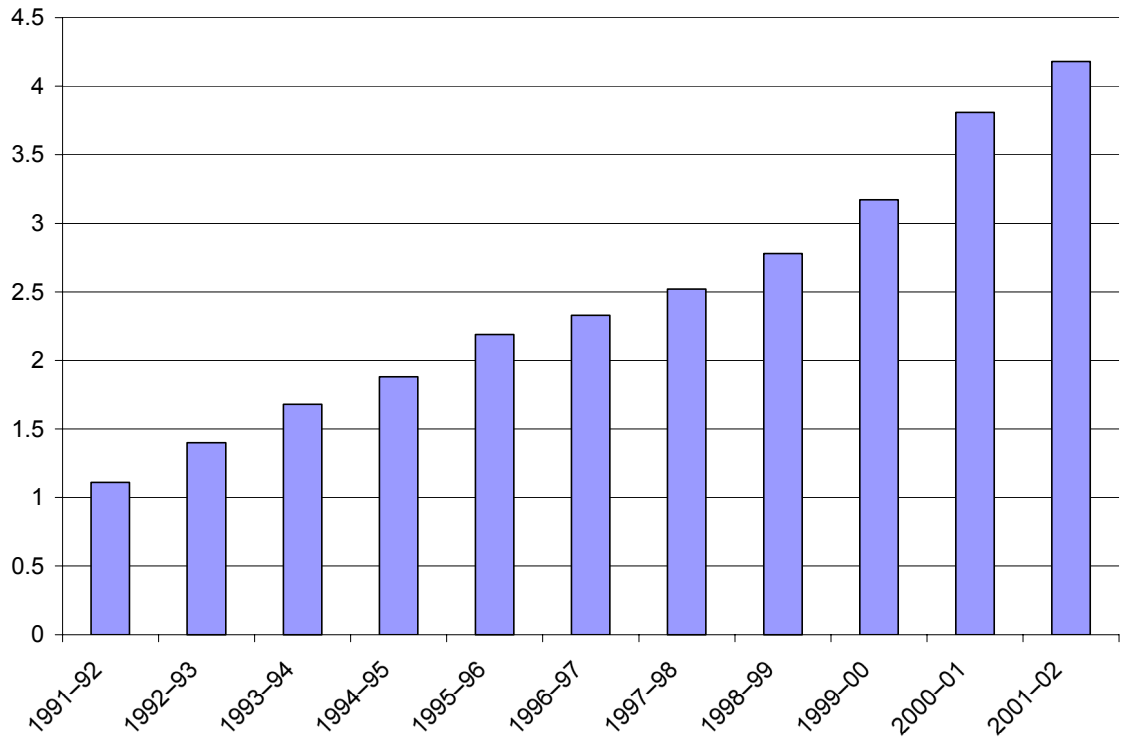
2. Implications of including the PBS in an Australia-US FTA

2.1 The Pharmaceutical Benefits Scheme

The Australian PBS has been in operation since June 1, 1948. The scheme was established in response to concerns that not all people could afford valuable new medications such as penicillin (DoPL 2003). The PBS subsidises the cost to Australians of most essential pharmaceuticals. All Australian citizens are eligible, and the scheme contains fixed out-of-pocket expenses for patients. Safety net arrangements limit the financial burden of out-of-pocket expenditures to low-income and high-volume users, such as the elderly and those with chronic disease.

Figure 1 shows the growth in PBS expenditure by the Commonwealth Government over the period 1991-92 to 2001-02. It is important to note that while there have been larger than average increases in PBS expenditure in recent years, these followed several years of lower than average increases.

Figure 1 Total Commonwealth expenditure on the PBS 1991-92 to 2001-02 ($ billion)



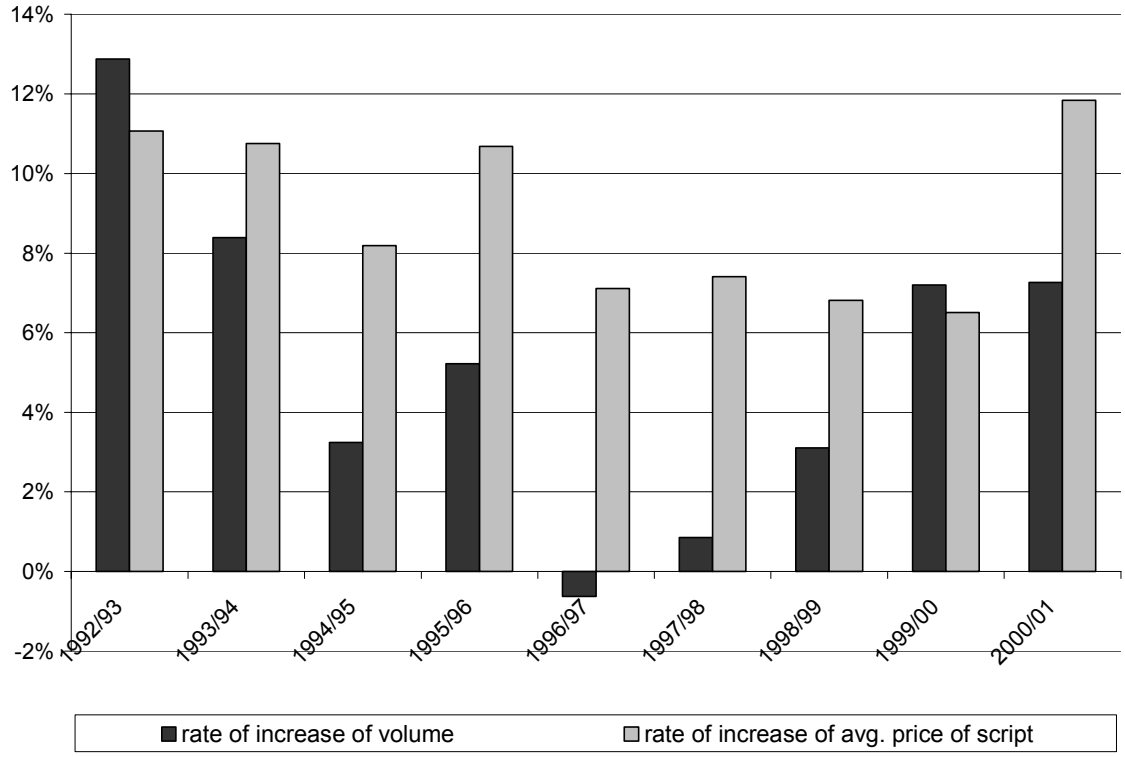
Source: Department of Health and Ageing, PBS Expenditure and Prescriptions, Table 17(b). (DoHA, 2002d) (Miscellaneous and section 100 drugs excluded).

Figure 2 shows that it is growth in the average price of PBS scripts rather than growth in the use of the PBS system that is primarily responsible for the increase in the cost to the Commonwealth of the PBS. Over the period 1991-92 to 2000-01 growth in the volume

of scripts averaged five percent per annum while the average price of scripts grew at nearly double that rate, averaging nine per cent per annum over the same period (DoHA 2002b).

Given the strong increase in average prices, it would appear that if the Government's objective is to control the cost to the budget, then further price controls rather than attempts to ration access to medicine would appear to provide the most effective approach.

Figure 2 Growth in PBS script volumes and growth in average price of scripts



Source: DoHA (2002d) Table 17(a) and 17(b)

Controlling demand for pharmaceuticals is central to any attempt to control the cost of drugs to the budget. However, the marketing of drugs designed to increase demand is an important strategy for manufacturers seeking to increase profit. While direct-to-consumer marketing for prescription drugs is illegal in Australia, other forms of promotion are available, in particular the marketing of pharmaceuticals to prescribing doctors.

Table 1 shows the number of drug substances that are listed on the PBS, along with the number of different varieties and strengths of drugs and the number of different brands of drugs currently available. While the number of drug substances listed has risen by only 13 per cent since 1995, brand names have increased by 48 per cent. Despite the fact that identical drug compounds have identical effects on the human body, Table 1 shows that pharmaceutical companies are dedicating an increasing amount of resources

to product differentiation, an expensive strategy that can only yield benefits if consumers can be persuaded that one 'brand' is superior to another.

Table 1 Number of drugs listed on the PBS

	Drug substances	Item forms and strengths	Brand names
Nov-95	527	1207	1697
Nov-96	548	1247	1773
Nov-97	549	1285	1855
Nov-98	555	1347	1968
Nov-99	570	1380	2065
Nov-00	587	1440	2252
Nov-01	589	1458	2459
May-02	593	1461	2506

Source: Department of Health and Ageing cited in DoPL (2003).

The top ten drugs included in the PBS, measured in terms of the cost to the Commonwealth Government, are shown in Table 2. The total cost to the Government of these drugs was over $1.3 billion in 2001-2002, accounting for more than 30 per cent of the entire PBS budget in that period.

Table 2 Cost to government of top ten brands, year ending June 2002 (excludes generic prescribing)

Rank	Drug	Volume of scripts	Cost to Govt. $	Total cost $	Ave price June 2002 $
1	Lipitor	5,196,628	269,412,718	314,283,143	60.48
2	Zocor	2,900,271	161,738,488	181,733,923	62.66
3	Zyprexa	567,350	120,074,399	123,208,268	217.16
4	Losec tablets	2,550,131	118,902,206	140,011,895	54.9
5	Celebrex	3,549,018	103,415,761	128,289,462	36.15
6	Pravachol	1,607,077	88,456,525	100,184,195	62.34
7	Vioxx	2,342,979	69,276,012	87,015,378	37.14
8	Somac	1,628,825	67,961,137	80,657,175	49.52
9	Zoloft	2,215,050	63,969,456	86,519,608	39.06
10	Seretide Accuhaler 500/50	772,519	55,388,896	62,179,892	80.49

Source: DoHA (2002b) Table 14a

2.2 Why pharmaceutical price regulation was introduced in Australia

In the mid 1960s it was found that international pharmaceutical manufacturers were charging the Australian government significantly higher prices for essential medicines than the United Kingdom government (Sloan 1995). On 27 August 1963, the Minister for Health, the Honorable H W Wade, reported to Cabinet on the subject of 'Drug costs - UK-Australian parity'. He stated that:

> There are some glaring cases of apparent exploitation of the Australian market by overseas manufacturers in this matter [drug prices]. For example, tetracycline,…costing the Commonwealth some 6 million pounds per annum as a pharmaceutical benefit, is sold in England for (27 shillings and 1 pence) per 16 capsules and the Australian price is (38 shillings and 6 pence) per 16 (Cabinet Submission No.877 on 27 August 1963 quoted in Sloan 1995, p.12).

He went on to say that the Government could no longer accept the way that drug prices were determined (Sloan 1995, p. 13).

As a consequence, the Department of Health established pricing control mechanisms and instituted improved price negotiation mechanisms in its dealings with pharmaceutical manufacturers. In subsequent years the pricing and volume regulatory framework embodied in PBS committees such as the Pharmaceutical Benefits Advisory Committee (PBAC) and the Pharmaceutical Benefits Pricing Authority (PBPA) have been recognized internationally for achieving excellent value – for money for Australian taxpayers and pharmaceutical consumers.

These mechanisms have meant that despite the rapidly rising cost of new medical breakthroughs in pharmaceutical therapy, all Australians, regardless of income, have access to the latest medicines shown to be effective. International commentators frequently refer favourably to the Australian system. Professor Richard Laing of the Boston University School of Public Health has stated that Australia's PBS is the best in the world:

> Australia… is the one country which seems to have got it right, that what you want to do in controlling costs is to pay what the drugs are therapeutically worth. And the Pharmaceutical Benefits Scheme does that (Laing 2001).

2.3 The PBS listing and pricing process

For a new drug to be listed on the PBS approval for its sale must first be obtained from the Therapeutic Goods Administration (TGA). In assessing a request for the approval of a new drug the TGA is required to consider, amongst other things, the product's quality, safety and efficacy. If the TGA approves the drug for sale within Australia, the supplier may then apply to have the new drug listed for subsidisation on the PBS. In order to do so the supplier must apply to the Pharmaceutical Benefit Advisory Committee (PBAC), a committee of experts whose role is to assess applications for listing on the PBS against a number of criteria, including:

- the need for the product;
- the outcomes and costs of a particular pharmaceutical when weighed against other available therapies; and
- whether any restrictions should be imposed on new listings (such as limits on the number of items that may be prescribed or restrictions on the indications for which a PBS subsidy is available).

The *National Health Act 1953* requires that the PBAC can recommend a new drug for listing only if it addresses an unmet medical need or provides a significant improvement in efficacy or a reduction in toxicity over drugs in the existing listing and is of acceptable cost-effectiveness (DoHA 2003). This provision is important as it ensures that new drugs will be listed only if there is evidence that an improved outcome for patients and the community will be delivered.

Once a new drug has been listed by the PBAC, the Pharmaceutical Benefits Pricing Authority (PBPA) will then set the price that should be paid to the manufacturer. The PBPA may also stipulate conditions on use, such as restrictions on prescription to specific groups. The Department of Health, acting on behalf of the Commonwealth Government, is then responsible for negotiating a price with the drug supplier. The Government makes the final decision whether to list the drug at the negotiated price. This process is discussed in detail in Productivity Commission (2001).

Pharmaceutical companies are opposed to this approach to price determination, describing the impact of the PBS on the pricing of pharmaceuticals as 'insidious' (Medicines Australia 2002, p. 25). Pharmaceutical manufacturers would prefer a system in which they have the freedom to market their products and set prices according to the market's willingness to pay.

US drug manufacturers have expressed concern with the 'overriding focus on cost-effectiveness' of the PBS and have taken issue with the Australian requirement that 'To obtain a premium, the applicant must demonstrate significant clinical advantages over its main comparator and satisfactory cost-effectiveness versus that comparator'. (PhRMA 2003).

2.4 Arguments for deregulating the PBS

While the success of the PBS system in controlling the price of pharmaceuticals in Australia (Productivity Commission 2001) makes it difficult to envisage why the system should be scrapped, it is important to consider the arguments put forward by the US and international pharmaceutical industries and their representatives in Australia.

The first argument is that 'paying a reasonable (return) price to the innovator will lead to recognition that Australia is willing to pay its fair share of the overall R&D costs' (Medicines Australia 2002, p. 22). While the argument that there is a need to fund R&D appears compelling, a recent report by Families USA examined R&D expenditures in the pharmaceutical industry in relation to other spending and total profits (FUSA 2002). These findings are echoed in the work of Henry and Lexchin (2002).

The FUSA study shows that R&D expenditures are less significant than marketing costs, for example, and that the pharmaceutical industry has been the most profitable industry in the US for over a decade. It is therefore difficult to justify the high cost of pharmaceuticals based on R&D arguments alone. A comparison of profits, expenditure on marketing and administration and expenditure on R&D for major US drug companies is provided in Table 3.

Table 3 Outlays of major US drug companies, 2001

Company	R & D (% of revenue)	Marketing/ advertising/ administration (% of revenue)	Profit (net income as % of revenue)	Revenue (net sales, US$ million)
Merck & Co., Inc.	5%	13%	15%	$47,716
Pfizer, Inc.	15%	35%	24%	$32,259
Bristol-Myers Squibb Co.	12%	27%	27%	$19,423
Abbott Laboratories	10%	23%	10%	$16,285
Wyeth	13%	37%	16%	$14,129
Pharmacia Corporation	16%	44%	11%	$13,837
Eli Lilly & Co.	19%	30%	24%	$11,543
Schering -Plough Corp.	13%	36%	20%	$9,802
Allergan, Inc.	15%	42%	13%	$1,685
Average	11%	27%	18%	
Total (million)	$19,076	$45,413	$30,599	$166,678

Source: FUSA, 2002

Table 3 shows that all but one company spent more than twice as much on marketing, advertising and administration as they did on research and development. On average, the nine companies reported profits of 18 per cent of total revenue, but only 11 percent of total revenue was allocated to R&D. Furthermore, the net profit of six out of the nine companies exceeded expenditure on research and development in 2001.

FUSA also considered the relative profitability of the pharmaceutical industry in the US compared to other US industries (FUSA 2002). They concluded that it had been the most profitable industry in America for each of the past ten years and, in 2001, was more than five times more profitable than the median Fortune 500 company. A list of the most profitable industries in the Fortune 500 between 1991 and 2001 is provided in Table 4.

Table 4 Pharmaceutical industry Fortune 500 ranking (return on revenues)[1]

	Drug Industry rank	% Return	Industry ranked number 2	% return	Fortune 500 median return %[2]
1991	1	12.8	beverages	5.5	3.2
1992	1	11.5	toys, sports goods	6.5	2.4
1993	1	12.5	publishing, printing	6.4	2.9
1994	1	16.1	commercial banks	13.5	4.6
1995	1	14.4	commercial banks	13.3	4.8
1996	1	17.1	commercial banks	13.9	5.0
1997	1	16.1	commercial banks	13.6	4.9
1998	1	18.5	commercial banks	13.2	4.4
1999	1	18.6	commercial banks	15.8	5
2000	1	18.6	commercial banks	14.1	4.5
2001	1	18.5	commercial banks	13.5	3.3

1. Prior to 1993, return on sales.
2. Median return on revenues for all Fortune 500 companies.
Source: Fortune Magazine's annual rating of the industries, 1992-2002 (cited in FUSA 2002).

The pharmaceutical industry is also very generous to its top executives offering them millions of dollars in annual pay, supplemented by even larger company stock options. The ten highest-paid executives across the nine companies received a total of US$236 million in remuneration in 2001, averaging US$23.6 million each. The highest-paid of these executives was the CEO of Bristol-Myers Squibb, C.A. Heimbold, Jr., who in 2001 received an income of US$74.9 million. The compensation, exclusive of unexercised stock options, for the highest paid pharmaceutical executives is shown in Table 5.

Table 5 Annual compensation of the ten highest paid pharmaceutical executives (excluding unexercised stock options) US$ 2001

Executive Name	Title	Company	Annual Compensation
1. C.A Heimbold, Jr	Former Chairman and CEO	Bristol-Myers Squibb Co.	$74,890,918
2. John R. Stafford	Chairman	Wyeth	$40,521,011
3. William C. Steere	Former Chairman	Pfizer Inc.	$28,264,282
4. Henry A. McKinnell	Chairman and CEO	Pfizer Inc.	$23,759,405
5. John F. Niblack	Vice Chairman	Pfizer Inc.	$15,920,178
6. Francis R. Tunny	Corporate VP, Admin and Sec.	Allergan, Inc	$12,306,468
7. Raul E. Cesan	Former President and COO	Schering-Plough Corp.	$11,308,409
8. Miles D. White	Chairman, CEO, and Director	Abbott Laboratories	$10,631,733
9. David L. Shedlarz	Executive VP and CFO	Pfizer Inc.	$9,497,231
10. Karen L. Katen	Executive VP, Pres. Pfizer Pharm Grp, Pres. US Pharm	Pfizer Inc.	$8,972,162
Total			$ 236,071,797
Average			$ 23,607,180

Source: FUSA, 2002

It is quite clear that research and development is not constrained by a shortage of money, with outlays on administrative and marketing expenditure and returns to shareholders far exceeding current levels of R&D expenditure.

The second argument for deregulation of the PBS is that price controls delay or prevent patient access to new therapies. The evidence does not support this assertion. A report by the Productivity Commission (2001) found that for most countries there was no significant difference in the delay between the global and the local launch dates. For example, the delay between the global and Australian launch dates for new drugs is 2.2 years. This is similar to the results for Canada and NZ and not substantially longer than the figure for the US or Spain. These data are summarised in Table 6.

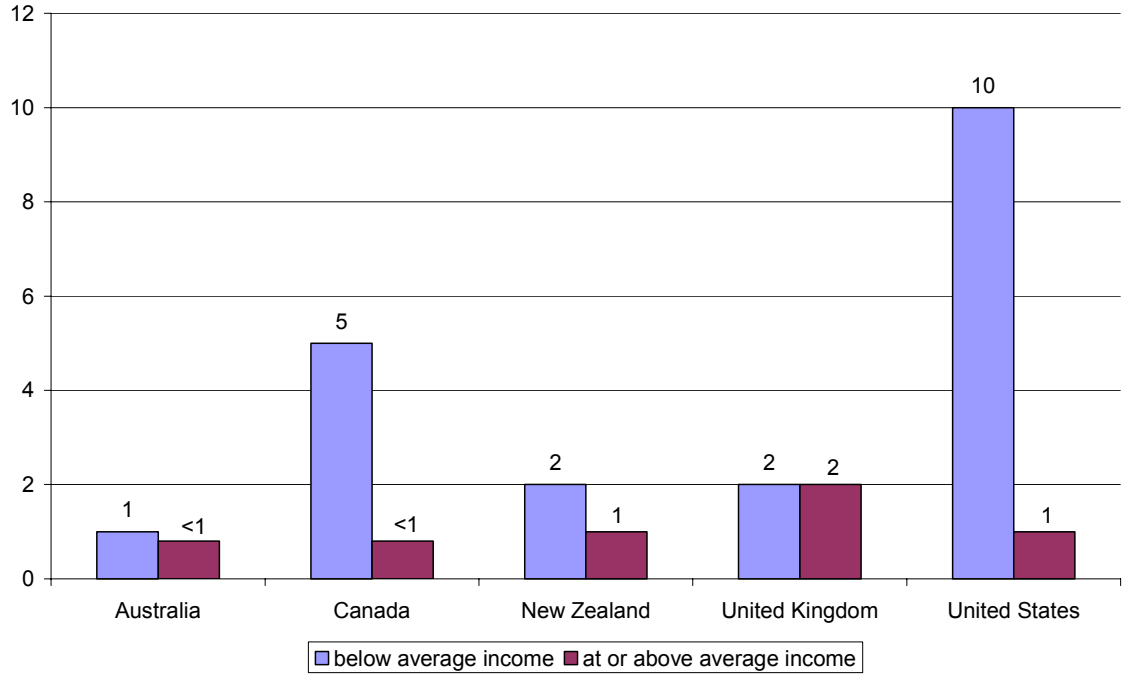
Table 6 Time from international launch to availability of medicine in domestic market (median value in years)

	US	Australia	France	Spain	Canada	NZ	UK
All drugs	3.5	3.4	3.3	3.3	3	2.8	0.9
New drugs	1.9	2.2	3.3	1.8	2.2	2.2	0.4

Source: Derived from Productivity Commission (2001, p. E24)

Moreover, if pharmaceutical companies are concerned with patient access to new medicines, then they should also be concerned with the impact of high prices on the affordability of new drugs. As shown in Figure 3, the proportion of elderly people who cannot afford to have a prescription filled is ten times higher in the US than in Australia.

Figure 3 Proportion of the elderly who could not afford to fill a prescription in the past year (1999)



Source: Schoen *et al*. (2000).

Although the Australian Government and segments of the Australian community may be concerned about the 'crisis' in the cost of pharmaceuticals, the concern is not uniquely Australian. As the following quotation suggests, adopting the US approach to supplying pharmaceuticals will not protect Australia from rising costs — quite the reverse. As New York Attorney General Eliot Spitzer said recently:

> New Yorkers face a health-care crisis — a crisis driven to a large degree by the enormous growth in the cost of prescription drugs. This cost explosion is eroding individuals' health care and is a large factor in the massive state deficit (Spitzer 2003).

2.5 The influence of the pharmaceutical industry in the US

The pharmaceutical industry has considerable influence with the current US Administration. During the 1999-2000 election cycle in the US, and with billions at stake in a heated debate over prescription drug prices at home and a growing number of patent disputes abroad, the industry gave disproportionate support to George W. Bush. In that election nearly 70 per cent of the industry's unprecedented US$24.4 million campaign contributions was spent on Bush and other Republicans (Borger 2001).

Since coming to office President Bush has appointed several advisers with close ties to the pharmaceutical industry. Mitch Daniels, the Director of the Office of Management and Budget, was previously the senior vice president of the Indianapolis-based pharmaceuticals firm Eli Lilly and Company (TIS 2001). The Office of Management and Budget is responsible for preparing the President's budget proposals to Congress.

Defense Secretary Donald Rumsfeld has previously served as Chief Executive Officer, President, and then Chairman of G.D. Searle & Co., a worldwide pharmaceutical company (USDD 2003). Until being sworn in as the 21st Secretary of Defense, Mr. Rumsfeld served as Chairman of the Board of Gilead Sciences, Inc., another pharmaceutical company (Gilead 1997).

It was due largely to lobbying from this industry that the US insisted on the inclusion of the Agreement on Trade-Related Aspects of Intellectual Property Rights (TRIPS) as a mandatory part of the World Trade Organisation (WTO) umbrella of trade agreements (Drahos and Braithwaite 2002). According to Peter Drahos and John Braithwaite of the Australian National University, 'a small number of US companies captured the US trade-agenda-setting process and then, in partnership with European and Japanese multinationals, drafted intellectual property principles that became the blueprint for TRIPS' (Drahos and Braithwaite 2002 p. 12).

TRIPS was used by international pharmaceutical companies to argue that the South African government did not have the right to import the cheapest HIV medicines (for example, from India) to tackle the AIDS pandemic affecting that country (Drahos and Braithwaite 2002, p. 7). In 1998, 41 pharmaceutical companies began proceedings against the South African government and President Mandela after he signed a bill to allow the importation of HIV medicines from the cheapest international sources.

The pharmaceutical industry has been most successful in using its influence to maintain prices and profit margins in the US. When US legislators have sought to address the issue of unregulated pharmaceutical prices, the industry has been swift to respond. For example, the American pharmaceutical industry body, PhRMA, recently took the US state of Maine to court for attempting to introduce legislation similar to the PBS. Maine legislators realised the need for such a program when they found that:

> the citizens of Maine have been denied access to medically necessary drugs due to the excessively high prices being charged by pharmaceutical companies. The inability of Maine's citizens to pay for these drugs often results in costly — and otherwise avoidable — hospitalization or institutionalization. Second, Maine residents pay much higher prices for drugs than do citizens of other countries (Phelps 2001, p. 4).

According to the Governor of Maine, Angus King, under the new legislation 'ordinary people will be able to get the drugs they need without necessarily having to face the terrible choice between the rent, the food, and the medicine' (Barrington 2002, p. 3).

Similarly, PhRMA filed lawsuits to stop the state of Florida from introducing a law requiring drug manufacturers to provide discounts if they wanted their drugs to be included on a list of preferred drugs for recipients of Medicaid. Florida Governor Jeb Bush stated 'protecting the large profit margins for multibillion-dollar pharmaceutical companies is not a priority. We are more concerned about making sure our senior citizens have better access to affordable prescription drugs' (Tieman 2001, p. 31).

It appears that US politicians are becoming increasingly aware of the failures that have resulted from allowing the market system to determine the price of essential goods such as medicines. It is, perhaps, ironic that just as US governments are addressing these flaws, the Australian government is considering moving toward the US approach.

2.6 The influence of the pharmaceutical industry in Australia

US pharmaceutical manufacturers are also influential in Australia. In the last few years the industry has moved to establish high-level representation and used a variety of strategies to lobby against PBAC mechanisms that are vital to the viability of the PBS (Jackson 2001).

Publicity over pharmaceutical industry influence in reforms to the PBAC highlight the industry's influence in Australia's political process (Jackson 2001). The former Minister for Health, Michael Wooldridge, was criticised for removing several long standing members of the PBAC and appointing an industry representative to the board. One of those removed was Professor David Henry who, as chairman of the economic subcommittee of the PBAC, had built an international reputation as an expert in determining the cost-effectiveness of new drugs. His removal was, he believed, a result of intense lobbying by the pharmaceutical industry and an attempt by the Howard Government to appease industry frustration at what it claimed were Australia's overly restrictive drug listing and pricing policies (Davies 2001).

In addition to the direct lobbying of parliamentarians, the industry has hired numerous former Liberal party staffers to facilitate access to, and influence over, the Commonwealth Government. Kieran Schneemann, formerly chief advisor to Finance Minister Nick Minchin, was recently appointed CEO of the Australian drug industry lobby group, Medicines Australia (Metherell 2002). He replaced Alan Evans who was a First Assistant Secretary at the Department of Industry prior to his role as CEO (Jackson 2001). More recently, Health Minister Kay Patterson's senior adviser on the PBS left to take a position with Merck Sharp and Dohme, a large pharmaceutical company (Probyn 2003, p.12). This continues a trend which began under former Health Minister Michael Wooldridge whose key adviser, Rachel David, and staffer, Ken Smith, both left Government to work as consultants for the pharmaceutical firm Pfizer (Davies 2001).

Given the industry's influence within both the US and Australian governments and its widely expressed dissatisfaction with the cost control and profit limiting measures of

the PBS, it is likely that Australian negotiators will face substantial pressure to make changes to the operation of the PBS during the negotiation of the Australia-US FTA.

The refusal by the Government to exclude the PBS from the FTA negotiations makes it essential to analyse the benefits that flow to Australian citizens from the current system. The following sections analyse the impact of possible changes to the PBS on both the operation of the Australian health system and on individuals using that system.

2.7 Effects on the price of medicines in Australia

Inclusion of the PBS in an Australia-US FTA would potentially remove many regulatory controls that ensure the current scheme meets the first objective of the National Medicines Policy, namely the 'timely access to the medicines that Australians need, at a cost individuals and the community can afford' (DoHA 2000, p. 1). As discussed previously, these controls were established in the 1960s when Australian legislators realised that an unregulated or free market in the pharmaceutical industry could result in significant detrimental consequences to the community.

Examination of the pharmaceutical industry reveals that it contains few of the elements required for the successful operation of a free market. First, mergers in the industry over the last decade have resulted in an oligopolistic market where suppliers have significant power to influence prices and purchasing decisions. Secondly, the international system of patent protection provides manufacturers with 20 years or more of a monopoly over their products. Thirdly, as many pharmaceutical products are life saving or essential for the maintenance of quality of life, patients are not in a position to refuse to purchase a product because a manufacturer has set an unreasonable price. In other words, demand is relatively insensitive to changes in price and patients will forgo other essential goods in order to purchase medicines. Finally this demand inelasticity is combined with significant information asymmetries which result in patients being unaware of the true worth or quality of pharmaceutical products.

In a deregulated environment these conditions enable manufacturers to exploit the characteristics of medicines to extract monopolistic prices from patients, as has been the case in the US (USHoR 1999). Under such conditions prices are unrelated to the cost of development or the therapeutic worth of products and are, instead, based on monopolistic profit maximisation calculations.

A number of studies have found that Australians pay less for pharmaceuticals than citizens of almost all other developed countries (Salkeld 1999, p.119; PC 2001). The pharmaceutical industry, and most commentators, agree that this is due to the PBS (Productivity Commission 2001; Medicines Australia 2002; PhRMA 2003). The industry claims that the Government uses its monopsony position to suppress prices unfairly (Medicines Australia 2002; PhRMA 2003). However, it is fair to expect a national government to use its buying power to increase the wellbeing of its citizens rather than allow private firms to extract monopoly profits.

The industry has consistently lobbied against PBS pricing regulations. In order to understand the objectives of the pharmaceutical industry it is useful to examine recent

recommendations made to the Government by Medicines Australia.[1] The report *A Prescription for the Future Health of Australia* (Medicines Australia 2002) states that the measures (in the PBS) that have the most 'insidious' pricing impacts are:

- Weighted Average Monthly Treatment Costs methodology which erodes the prices of innovative medicines over time.
- The use of low priced, and off-patent comparators in cost-effectiveness process;
- The use of generic price reductions to drive price reductions in linked agents post PBS listing;
- The focus on total cost considerations rather than cost-effectiveness alone;
- The push for price volume agreements;
- In addition, companies' return on investment through price is restricted by measures including the inability to charge a premium (Medicines Australia 2002).

The report concludes that '… global companies are increasingly reluctant to list products in Australia because of the potential of flow-on effects to prices in other countries' (Medicines Australia 2002, p. 25).

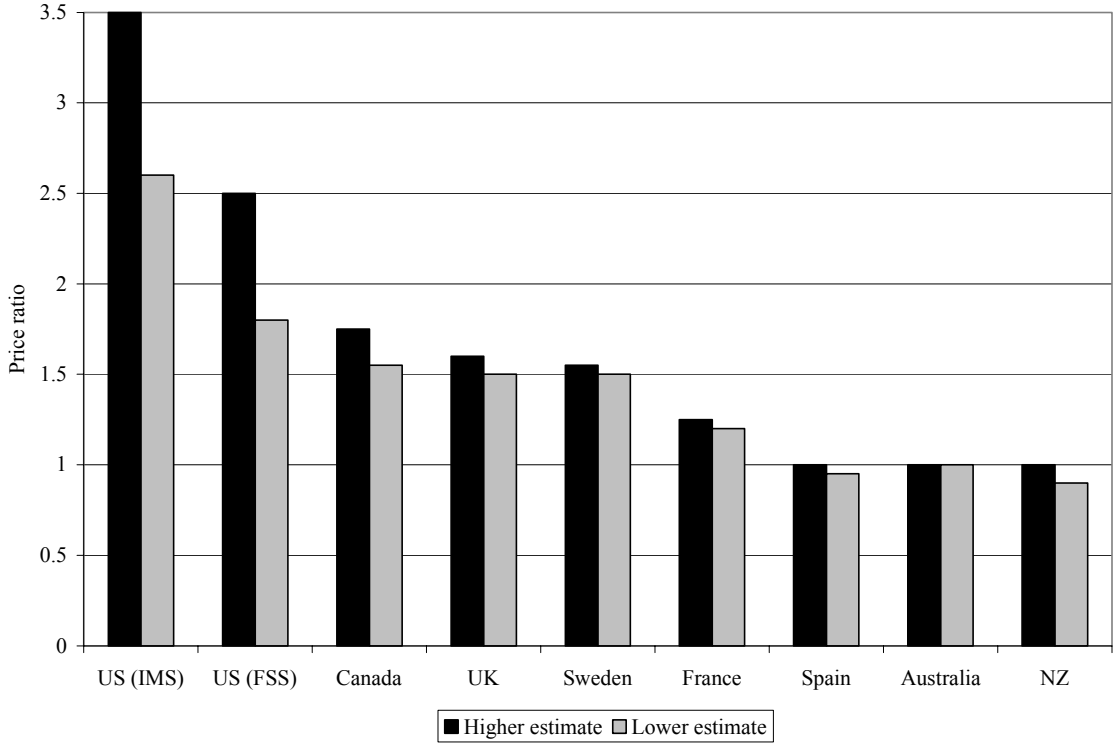
Given the pharmaceutical companies' own statements, it is clear that the price that Australia pays for medicines will rise if deregulation occurs. The magnitude of the increase is likely to be significant. The report by the Productivity Commission (2001) into international pharmaceutical price differentials is useful in estimating the size of such an increase. The Productivity Commission examined 150 top-selling PBS pharmaceuticals which account for over 80 per cent of total expenditure and compared prices for similar products in several developed countries. The study found that prices for Australia's top-selling medicines are on average:

- at least 162 per cent and up to 250 per cent higher in the US for individual patients purchasing retail medicines; and
- at least 48 per cent and up to 81 per cent higher in the UK, Canada and Sweden.

Figure 4 shows the differences in pharmaceutical prices between Australia and a range of other developed countries.

[1] The representative body of local subsidiaries of international pharmaceutical manufacturers.

Figure 4 International price differences – all categories of pharmaceuticals (Australia = 1)



Note: IMS refers to IMS Health and FSS the Federal Supply Schedule. The Productivity Commission relied on two different data sources when making its comparison.
Source: Productivity Commission 2001, p. XXIII

Importantly, countries where the price differential was the greatest (US and UK) have the least regulation of pricing (Productivity Commission 2001, pp. B30-37). By contrast, New Zealand, where pricing controls are even more stringent than in Australia, enjoyed the lowest prices of all countries examined (Productivity Commission 2001, p. B15). While differences in health systems, demand conditions, patent laws and production costs (including marketing and liability) make it difficult to use these international comparisons to determine prices in a deregulated environment in Australia, it is likely that prices will rise significantly if deregulation occurs (Productivity Commission 2001, p. 90).

Given the success of the PBS in achieving the stated aims of the National Medicines Policy, the onus of proof rests on advocates of deregulation to show why prices will not rise to those of comparable developed countries. Given the absence of any such evidence, it is reasonable to use international price comparisons with developed countries to forecast the likely impact of deregulation of price controls in Australia. It is also important to ask one question of the pharmaceutical industry: if it does not believe that deregulation will lead to increased prices and profits, why is it advocating it?

Based on the Productivity Commission estimates of prices in countries with minimal regulation such as US and the UK, it is reasonable to assume that, in the absence of an effective PBS, the average price of listed pharmaceuticals would rise by at least 50 per cent, and possibly up to 250 per cent. A 50 per cent increase in the average price of pharmaceuticals following deregulation would mean that Australian consumers of the public health system would pay an additional $2.4 billion to purchase the same pharmaceuticals they bought in 2002.[2]

The pharmaceutical industry concedes that prices are likely to rise following deregulation and quote the (conservative) figure of $1 billion a year (Evans 2002). Although the Government has commissioned a number of studies to determine the economic benefits to Australia of the proposed Australia-US FTA, no information has been released publicly on the likely social and distributional impacts of such an arrangement. Such information is, however, essential in determining whether an FTA is in the national interest.

It is possible to estimate the distributional impact of increases in pharmaceutical prices. Tables 7 and 8 provide estimates of the likely impact of increased pharmaceutical prices under a range of different scenarios. The major variables are the total growth in the cost of pharmaceuticals and how that growth is distributed between the Government, individuals with concession cards and individuals without concession cards. It would be inconsistent with its stated aim of reducing the cost of drugs to the budget for the Government to deregulate the pharmaceutical industry in a situation where it would bear all of the increase in costs.

Tables 7 and 8 assume that any higher pharmaceutical costs associated with deregulation will be borne by individuals rather than by the budget. The total increase in the cost of pharmaceuticals in a deregulated system is considered with reference to two scenarios. The first scenario, based on the public statements of the pharmaceutical manufacturers, shows the impact of a $1 billion dollar increase in costs. The second scenario, which shows the impact of a $2.4 billion dollar increase, is based on the lowest estimate of the Productivity Commission of the price discount Australians currently receive due to the PBS.

While an increase in the cost of pharmaceuticals is a likely consequence of Australia and the US negotiating an FTA, the distribution of the cost increase between concession card holders and non-concession card holders will be determined by government policy. Both tables 7 and 8 show the impact on existing co-payments of an increase in the cost of pharmaceuticals under three different scenarios, namely, non-concession card holders bearing 100 per cent, 50 per cent and 16 per cent of the total increase. The figure of 16 per cent was included as non-concession card holders currently account for this percentage of total pharmaceutical costs.

[2] Based on total PBS expenditure of $4.99 billion, http://www.health.gov.au/pbs/pubs/pbbexp/pbjun02/bookp02.pdf

Table 7 Impact of a $1.0 billion increase in the cost of pharmaceuticals to consumers

Payment type	Non-concessional		Concessional	
	Co-payment	Increase	Co-payment	Increase
Current co-payment	$23.10		$3.70	
100% borne by non-concession card holders	$64.59	180%	$3.70	0%
50% borne by non-concession card holders	$43.84	90%	$7.53	104%
16% borne by non-concession card holders	$29.74	29%	$10.14	174%

Table 7 shows that if the cost of pharmaceuticals rises by $1 billion, and that cost is borne entirely by non-concession card holders, then the co-payment for this group will need to rise to $64.59, a 180 per cent increase on the current co-payment. Alternatively, if the Government decides to require concession card holders to pay a proportionate share of the increased cost of pharmaceuticals then a concessional co-payment would increase by 174 per cent to $10.14. If this were the case, the cost of a non-concessional co-payment would only need to increase by 28 per cent to $29.74.

Table 8 Impact of a $2.4 billion increase in the cost of pharmaceuticals to consumers

Payment type	Non-concessional		Concessional	
	Co-payment	Increase	Co-payment	Increase
Current co-payment	$23.10		$3.70	
100% borne by non-concession card holders	$122.66	431%	$3.70	0%
50% borne by non-concession card holders	$72.88	216%	$12.90	249%
16% borne by non-concession card holders	$39.03	69%	$19.16	418%

Table 8 shows the impact of a $2.4 billion increase in the cost of pharmaceuticals. Under such circumstances, if the entire cost of the increase were to be borne by non-concession card holders, then co-payments would need to rise more than 431 per cent to a maximum of $122.66 per script. Once again, if the cost increase were allocated in proportion with the current distribution of pharmaceutical costs and concession card holders bore 84 per cent of the increase, then concessional co-payments would need to rise by 417 per cent to $19.16.

Both Tables 7 and 8 assume that the entire increase in the costs of pharmaceuticals resulting from the implementation of changes to the PBS such as those sought by the pharmaceutical industry will be borne by consumers. It is, however, possible that the Government could elect to fund a portion of the increase in the costs of pharmaceuticals flowing from an FTA with the US by increasing tax revenue or reducing government expenditure in other areas.

Tables 9 and 10 show the likely increase in the cost of pharmaceutical scripts if the Commonwealth Government were to fund half of the increase in costs from the budget and pass half on to the price of prescriptions. Table 9 shows the impact of a $1 billion dollar increase in the total cost of pharmaceuticals, of which half is funded from the budget. Table 10 shows the impact of a $2.4 billion dollar increase in the costs of pharmaceuticals, of which half is funded from the budget.

Table 9 Impact of a $1.0 billion increase in the cost of pharmaceuticals (with half the increase met from the budget)

Payment type	Non-concessional		Concessional	
	Co-payment	Increase	Co-payment	Increase
Current co-payment	$23.10		$3.70	
100% borne by non-concession card holders	$43.84	90%	$3.70	0%
50% borne by non-concession card holders	$33.47	45%	$5.62	52%
16% borne by non-concession card holders	$26.41	14%	$6.92	87%

Table 9 shows that even if the cost of pharmaceuticals rises by the $1 billion estimated by the pharmaceutical industry, and if half of that increase is absorbed through the budget, substantial increases in the cost of pharmaceuticals will still occur. If, for example, the cost increases are shared evenly between concession card holders and non-concession card holders, then the price of a prescription would still rise by over 44 per cent for non-concession card holders and by over 51 per cent for concession card holders.

Table 10 Impact of a $2.4 billion increase in the cost of pharmaceuticals (with half the increase met through the budget)

Payment type	Non-concessional		Concessional	
	Co-payment	Increase	Co-payment	Increase
Current co-payment	$23.10		$3.70	
100% borne by non-concession card holders	$72.88	216%	$3.70	0%
50% borne by non-concession card holders	$47.99	108%	$8.30	124%
16% borne by non-concession card holders	$31.07	35%	$11.43	209%

Alternatively, if the cost of pharmaceuticals rises by $2.4 billion, even after $1.2 billion is absorbed by the budget. The cost of prescriptions is likely to double for both concession card holders and non-concession card holders alike, as shown in Table 10.

Given the Government's stated concern with the costs of pharmaceuticals to the budget, it is unlikely that a high percentage of the increased costs flowing from an FTA will be absorbed by the Commonwealth. As shown in the tables above, the smaller the percentage absorbed by the Government, the higher will be the price increases paid by those needing prescription medication.

2.8 Implications of deregulation for the viability of the PBS

In addition to the significant transfers of wealth from the Australian public to foreign pharmaceutical manufacturers, there is also a risk that deregulation will threaten the viability of the PBS. The PBS is unique in that it combines an uncapped subsidy scheme with fixed patient cost sharing arrangements that limit the cost to those with low incomes or significant usage requirements. Thus, for listed products which cover nearly 75 per cent of pharmaceuticals approved for use, most Australians can access essential medicines without facing financial hardship, although for some the existing co-payments create financial difficulties.

Despite the unique accessibility of the Australian scheme, supply side controls such as the restrictions placed on suppliers through the PBAC, have effectively constrained expenditures over the last decade. Demand side controls, on the other hand, typically take the form of high prices to discourage consumption. The major supply side controls used in Australia include:

- a positive subsidisation list incorporating cost-effectiveness evaluations;
- pricing controls such as reference pricing and price-volume agreements;

- volume restrictions, which limit use and require authority for certain high cost medicines; and

- restrictions on direct-to-consumer advertising.

Between 1990 and 2000 the average annual rise in expenditures on the PBS was 14.7 per cent. However, in 2000-01 there was a larger increase of 19.9 per cent. Stability returned in 2001-02 with growth of 9.9 per cent (DoHA 2002b). Rather than representing a failure of supply side controls, analysts have attributed the large increase in 2000-01 to the exploitation of loopholes in PBS regulations (Goddard 2002).

A major loophole in the current system is referred to as 'leakage'. Leakage refers to a process whereby pharmaceuticals are listed on the PBS because of their effectiveness in a narrow range of conditions. Once listed, however, they are marketed to doctors as being appropriate for treatment under a wider range of circumstances. This process allows manufacturers to meet the 'value for money' requirements of the listing process for new drugs by targeting applications for expensive medicines to narrowly defined groups of patients. Having achieved a PBS listing, there is no legislative barrier to prevent aggressive marketing of these products to doctors, thus expanding the market beyond that expressed in the initial application.

Health policy analysts have argued that further strengthening of PBS regulations would reduce the incentive to pursue this practice (Goddard 2002). Proposed solutions include the strengthening of price volume agreements to ensure that the price of a product falls if the anticipated volume is exceeded, as well as regular listing reviews to remove expensive medicines that can no longer be justified on cost-effectiveness grounds. It appears that the solution to achieving sustainable expenditures and maintaining the affordability of medicines is to strengthen existing supply side controls that have, to date, served the Australian public well.

Ironically, at a time when further support of PBS regulations are needed, there is the possibility that the entire system could be classified as a trade barrier under the Australia-US FTA and that Australia could be forced to weaken, or abandon, the current system. Deregulation of these crucial components of the current cost management strategies would create unsustainable cost pressures in coming years. Thus deregulation of supply side expenditure controls would have to be replaced by measures to restrict demand. As with market-based solutions in most deregulated sectors, the result would be to shift the cost of medicines to individual patients in the form of out-of-pocket payments (cost-sharing) at the time of utilisation (that is, illness).

Such changes are precisely the reforms that pharmaceutical manufacturers have recommended as part of the necessary complementary strategy to allow expenditure control in a deregulated PBS. Medicines Australia (2002) includes the following policy recommendations:

- measures to require consumers to assume greater responsibility for their health care and costs of medications; and

- a review of the co-payment with a view to introducing market signals into consumer choice, for example the elimination of the fixed co-payment scheme to a proportional co-payment system.

The Medicines Australia report goes on to acknowledge that some may not agree with these reforms on equity grounds, and makes the following comments in relation to the task of reforming co-payments.

> While the design of the new co-payment and safety net system … will need to be carefully targeted to minimize any significant impact on the disadvantaged group, that should not override the need to ensure that consumers take greater financial responsibility for their health (Medicines Australia 2002, p. 12).

While the major beneficiaries of such a change are likely to be international pharmaceutical companies, it is possible that the Government will consider itself better off if it succeeds in reducing the growth of the cost of the PBS to the budget. That is, the budget may benefit through the government taking responsibility for a smaller proportion of a bigger national pharmaceutical bill. Under such circumstances the budget's gain is the community's loss. Such cost shifting from the budget to the community is neither in the interests of the community as a whole nor of its poorest or sickest members who would carry a disproportionate share of any increases in out-of pocket expenses for pharmaceuticals.

2.9 Deregulation of restrictions on Direct to Consumer Advertising

Direct to consumer (DTC) advertising allows manufacturers to exploit the significant asymmetries of information between patient and producer in relation to the therapeutic worth of a product. The cost in both time and money of overcoming these asymmetries is prohibitive for individual consumers and this market failure is one of the rationales for committees like the PBAC. In effect the PBS (supported by the PBAC) is a collective purchasing unit which allows consumers to pool resources, employ experts, and benefit from the economies of information that this brings. Asymmetry of information between patient and pharmaceutical manufacturer is also a reason why, at the individual level, the need to take a medicine is a decision made for the patient by a physician with significant training in this regard.

DTC advertising provides manufacturers with a means to circumvent these mechanisms which were aimed at empowering consumers to purchase necessary medicines at an appropriate price. The consequences of this are two fold.

Firstly, brand loyalty created by DTC advertising encourages patients to demand more expensive brand named medicines from their doctors. This is despite the fact that the brand product may be medically inappropriate or therapeutically no better than cheaper generics or alternatives. In the pharmaceutical industry, as with other oligopolistic markets, DTC advertising creates brand loyalty through product differentiation by overselling the benefits of minor differences in medicines (for example, reductions in minor side-effects). The best evidence for this is the fact that the most heavily advertised products in deregulated markets such as the US are the so called 'me too' drugs which represent product differentiation rather than a therapeutic innovation.

'Me too' drugs are slightly differentiated versions of highly profitable medicines marketed by alternative manufacturers to ride on the success of the original. Profit in this class of medicines depends on winning a share of the market and is contingent on the success of advertising aimed at doctors as well as consumers.

The second adverse consequence of DTC advertising is that it induces demand for medicines in areas where pharmaceuticals may be inappropriate or inferior to non-pharmacological therapies. It encourages a 'magic pill' approach to social and lifestyle issues such as obesity, smoking, anxiety and cholesterol rich diets. Manufacturers have recognised a profitable product area in lifestyle illnesses such as obesity, anxiety, and heartburn which affect a significant proportion of the general population. Any increase in demand for these medicines as a result of DTC would lead to further pressure on the PBS budget.

Studies in the US have found that increased pharmaceutical expenditures were linked to increased DTC advertising (NIHCM 2000). A study by the National Institute for Health Care Management found that the 50 drugs most heavily advertised to consumers accounted for almost half of the $20.8 billion increase in US retail spending on pharmaceuticals from 1999-00; the remainder of the spending increase came from 9,850 prescription medicines that companies did not advertise or advertised very little (NIHCM 2000, p2).

The number of prescriptions in the US for the 50 most heavily advertised drugs rose 24.6 per cent between 1999 and 2000, compared to an increase of 4.3 per cent for all other drugs combined (NIHCM 2000, p2).

New Zealand and the US are the only developed countries that have lifted restrictions on DTC advertising. Reports from New Zealand show that this has had a detrimental impact on public health and public expenditures. A recent report on DTC advertising of prescription medicines in New Zealand written by senior academic staff at four of New Zealand's medical schools concluded that such advertising does not give objective information on risks, benefits and options to assist patients to participate in healthcare decisions (Burton 2003). The report provides the results of a survey of all 3200 general practitioners in New Zealand. More than three quarters of the 1611 respondents agreed that patients often asked for advertised drugs that were not appropriate for them.

It is therefore likely that a deregulated DTC advertising market in Australia would lead to a significant increase in expenditures as a result of supplier induced demand for brand named pharmaceutical products. If advertising of the top 50 drugs were as successful in Australia as it has been in the US, then the increase in the cost of pharmaceuticals would be in the order of hundreds of millions of dollars per year.

3. The impact of higher medicine prices in Australia

3.1 The impact of cost sharing on the Australian health system

While increased out-of-pocket financing may seem a convenient means of controlling public expenditure in a deregulated environment, there is substantial evidence to show that such an approach is problematic when applied to the health sector. Experience from Singapore and the US, for example, suggests that, unlike other commodities, health systems based on price signals and cost-sharing are likely to fail.

In 1984 Singapore reformed the government subsidised healthcare system in an attempt to introduce market forces and control demand by requiring patients to take financial responsibility for their health care. Ten years later, in its 1993 White Paper (SMoH 1993), the government declared that the experiment had failed, and that demand controls could not effectively hold down medical cost inflation. The government was forced to re-regulate the health system (Hsiao 2001; SMoH 1993).

The experience in Singapore shows that suppliers of health products and services can stimulate demand through advertising and other forms of marketing. Firms do not need to compete on price or quality as they can rely instead on gaining a competitive advantage through factors such as reputation. Such an approach is possible due to the significant information asymmetries that exist between health suppliers and patients. The result is that patients have difficulty assessing product quality, making pricing comparisons and determining whether a health procedure or product is essential or not. In such circumstances suppliers can exploit the insensitivity of demand for health products to changes in prices, especially for products that patients believe, or are led to believe, are essential.

A range of research demonstrates the detrimental impact that cost-sharing can have on health outcomes when the demand response to out-of-pocket expenses is likely to affect essential as well as non-essential health care (Dallek 1997).

1. The most rigorous study on cost-sharing was the RAND Health Insurance Experiment in the US (Newhouse 1985). The RAND Experiment found that cost-sharing discouraged people, particularly the poor, from seeking needed care. Among the low-income population, free care (no cost-sharing) led to a decline in the 'risk of dying'; and the absence of cost-sharing was especially beneficial for the study's low-income population.

2. Cost-sharing on prescription drugs may be especially harmful. The imposition of a nominal co-payment on prescription drugs resulted in US Medicaid beneficiaries selectively decreasing their use of drugs to treat life-threatening heart conditions and psychiatric conditions such as schizophrenia.

3. Cost-sharing penalises the sickest beneficiaries who require more health care services due to chronic and disabling diseases and who pay high out-of-pocket costs for their health care.

For many people health expenditures can have catastrophic financial consequences. To protect individuals, the financial impact of risk pooling must occur at the community level (for example, universal insurance and PBS-style safety net provisions such as annual caps) rather than at the individual level (for example, medical savings accounts). Prior to the introduction of universal insurance in Australia (Medicare), 'unpaid health service expenses were the highest cause of imprisonment for debt' (Scotton 1978, p.130).

Deregulated health systems with a heavy reliance on consumers assuming a 'greater responsibility for their health care and costs of medications' (Medicines Australia 2002, p. 12) are more characteristic of developing countries than developed countries. In ranking health systems in the *World Health Report 2000*, the degree of financial risk protection afforded by a country's health financing arrangements is one of three overall performance measures (WHO 2000). To score highly in relation to financial risk protection the WHO requires a country's health system to:

- reduce the exposure of families to large unexpected health expenses by 'minimizing the share of out-of-pocket financing of the system, so as to rely as fully as possible on more predictable prepayment that is unrelated to illness or utilization'; and

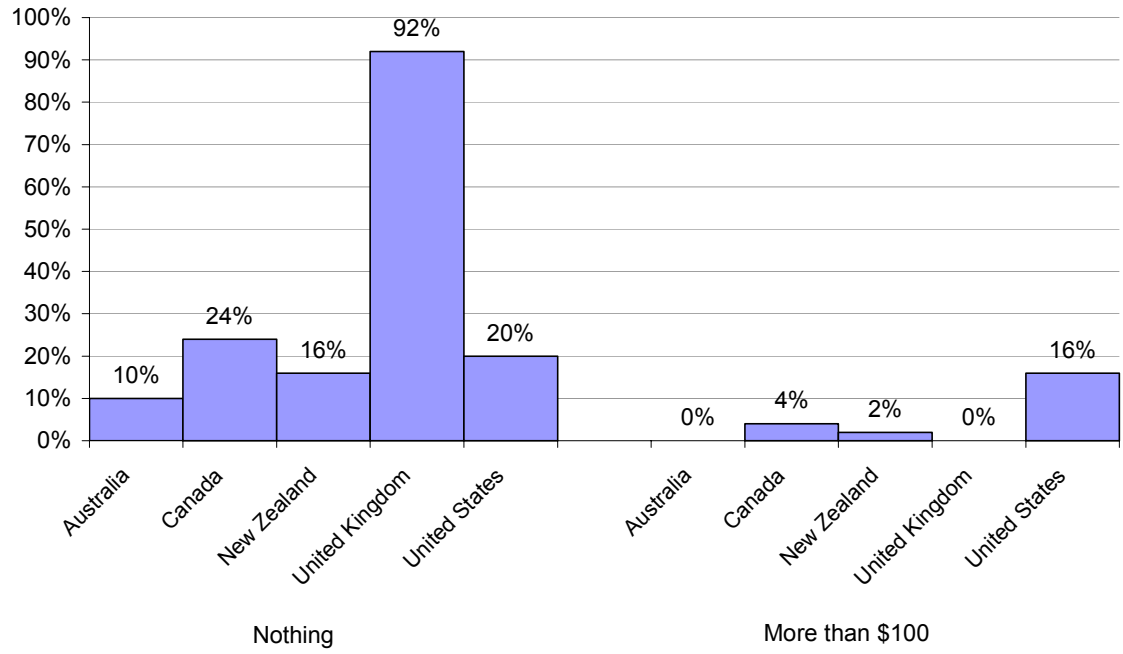
- avoid regressive prepayments for care by 'assuring that each form of prepayment – through taxes of all kinds, social insurance, or voluntary insurance – is progressive or at least neutral with respect to income, being related to capacity to pay rather than to health risk' (WHO 2000, p. 38).

In relation to the fairness of health financing arrangements the WHO ranks Australia 26-29th[3] in the world behind comparable developed countries like the UK, Germany, Canada, Sweden and New Zealand. This is a reflection of the current burden of out-of-pocket health expenses borne by individuals in Australia. In 1998 out-of-pocket payments accounted for 17 per cent of total health expenditures, that is, one in six dollars must be paid by patients at the time of illness. 'The main consumer payments are for pharmaceuticals not covered under the Pharmaceutical Benefits Scheme, dental treatment, the gap between the Medicare benefit and the schedule fee charged by physicians… and co-payments for pharmaceuticals' (EOHCS 2001, p. 36).

Figure 5 provides data on the distribution of health care costs among the elderly in Australia, Canada, New Zealand, the UK and the US. It shows that only ten per cent of the elderly in Australia spend nothing on health each month, compared to 92 per cent in the UK. It also shows that while 16 per cent of the elderly in the US spend more than $100 per month on prescription medicine, no elderly Australians spend such an amount. Based on international comparisons with comparable developed countries, it is difficult to argue that any increases in out-of-pocket costs to patients in Australia are desirable or necessary.

[3] The WHO rates countries in small bands rather than by individual country rankings.

Figure 5 Distribution of out-of-pocket monthly expenditures for prescription medicines by the elderly



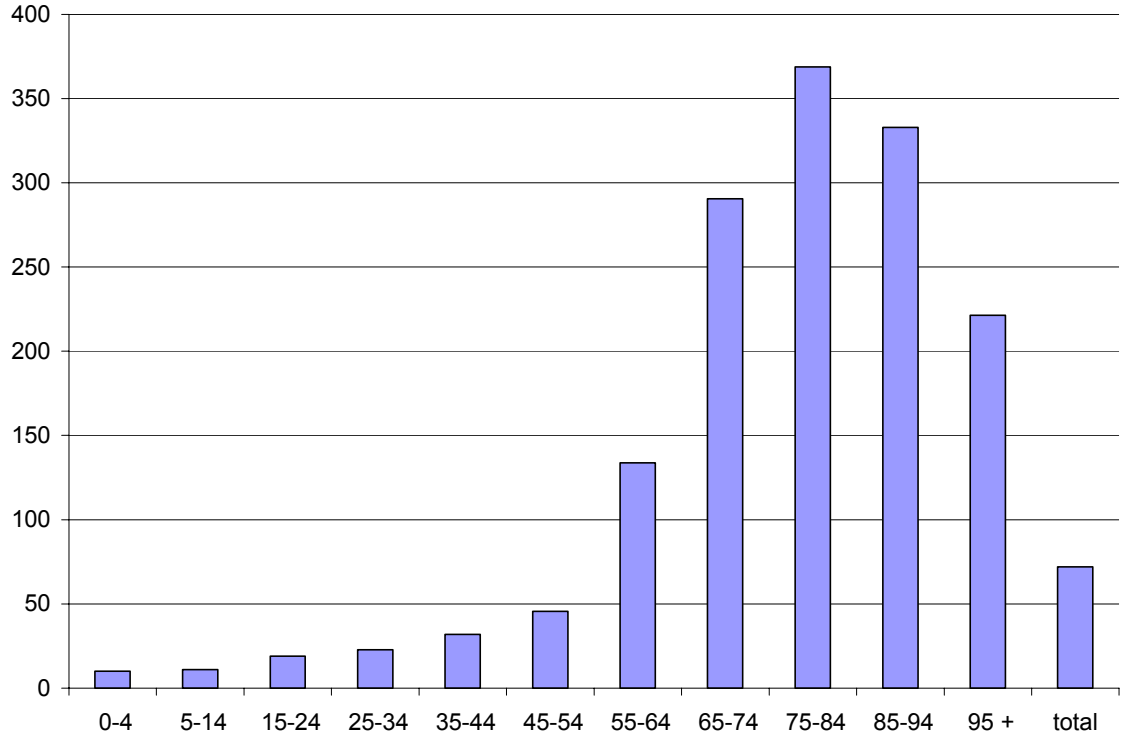
Source: Schoen *et al.* (2000).

3.2 The impact of out-of-pocket expenses on the elderly and the poor

Approximately 80 per cent of expenditure on PBS prescriptions is generated by concession card holders, particularly the elderly (DoHA 2002c). Therefore, to maintain expenditure control using cost-sharing mechanisms in a deregulated PBS system, concessional safety nets, fixed co-payments and annual expenditure caps would have to be relaxed or even removed.

Figure 6 shows the distribution of the costs to the government of PBS expenditure by age. Not surprisingly, the expenditure per person is markedly higher for older citizens than it is for the young. On average, people aged 75-84 receive more than seven times the benefits from the PBS than people aged 45-54.

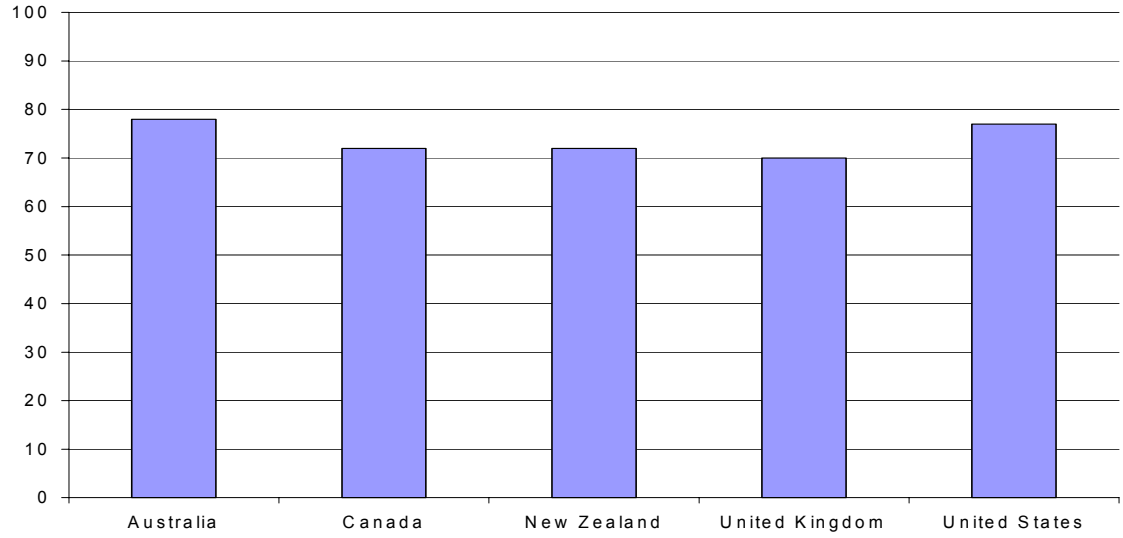
Figure 6 Average PBS cost per person by age (dollars)



Source: DoHA (2003b).

Australia is not unique in this regard; health costs typically increase with age and disease status. Figure 7 shows that reliance on prescription medicines by the elderly in Australia is comparable to other developed countries.

Figure 7 Percent of the elderly who have a medical condition that requires them to take prescription medication on a regular basis



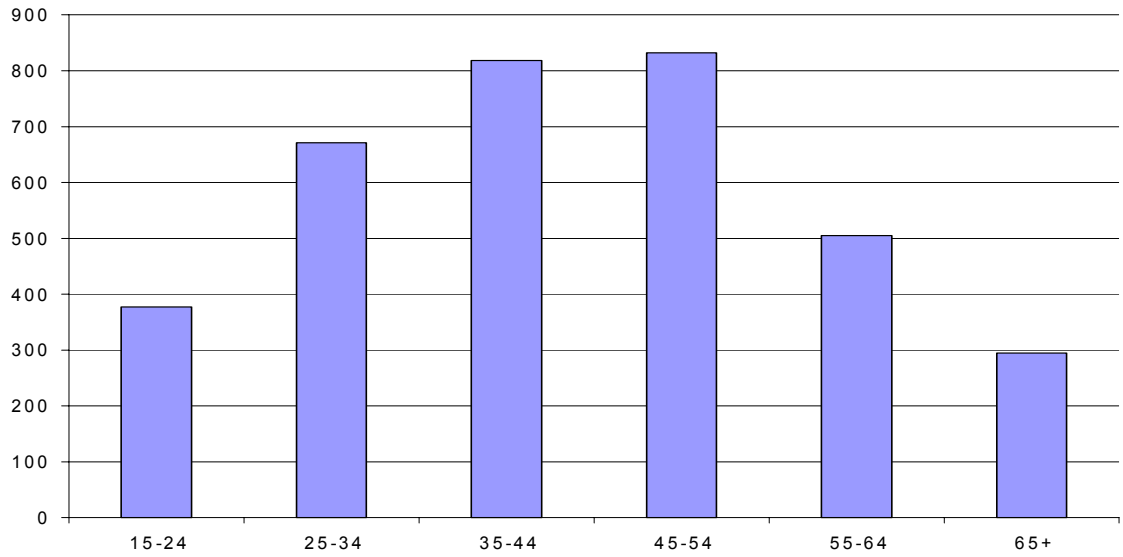
Source: Schoen *et al*. (2000)

Because of the heavy reliance of the elderly on the PBS it is difficult to discuss increased cost sharing for pharmaceutical purchases without considering the reduction or removal of existing safety nets. This is because the chronically sick and the elderly purchase more than 80 per cent of pharmaceuticals.

Figure 8 shows the distribution of income by age for Australia. For older Australians the median income is only 35 percent of the income of those aged 45-54. Combined with the much greater reliance of older people on pharmaceuticals (shown in Figure 6), the distribution of income by age creates both health and equity problems when individuals, rather than the government, bear the cost of illness. In a deregulated market, elderly Australians will be asked either to reduce their consumption of essential medicines or reduce their consumption of other goods and services. Given the low average income of the elderly, it is unlikely that major reductions in non-health goods and services can be easily achieved.

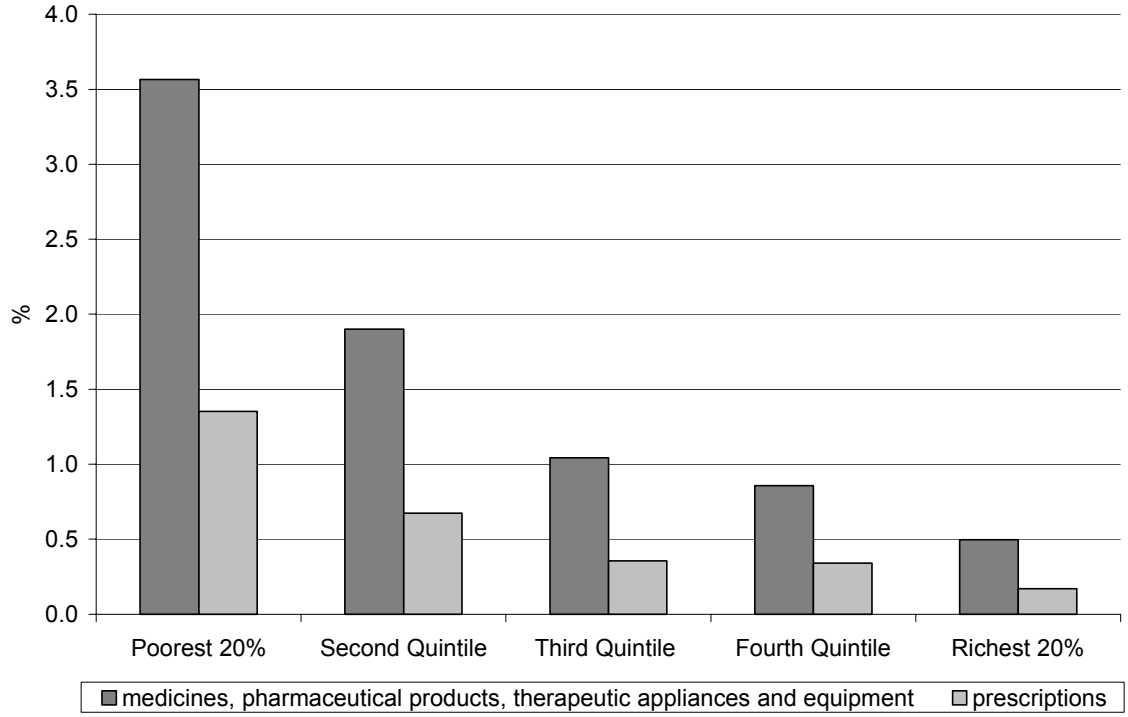
In addition to the specific problems faced by the elderly, with their combination of increased likelihood of chronic illness and lower than average incomes, all low income earners will suffer disproportionately from any deregulation of pharmaceutical pricing. As shown in Figure 9, low income earners, many of whom are elderly, spend a much higher proportion of their income on medicines than high income earners.

Figure 8 Australian Median weekly income by age, 2000 ($)



Source: ABS 2001, Income Distribution Australia, ABS cat. No. 6523.0, Table 4

Figure 9 Percentage of average weekly household income spent on medicines



Source: Household Expenditure Survey, ABS cat. No. 6535.0

Figure 9 shows that, as a proportion of income, the poorest 20 per cent of Australians spend seven times as much on medicines and other health products than the richest 20 per cent. Any increases in the cost of these products, as proposed by the pharmaceutical industry, will have a major impact on the spending patterns of this low income group.

International comparisons are again informative for estimating the impact on high-risk groups, particularly the elderly, of a move towards greater deregulation and reliance on higher prices to control demand. The financial burden faced by the elderly in the US, our potential partner in FTA liberalisations, serves as a note of caution. In the deregulated pharmaceutical market of the US, out-of-pocket expenditures and demand side controls have left the elderly, who make up 12 per cent of the population and use one-third of all prescription drugs, facing significant financial difficulties.

Commonwealth Fund (2000) found that 20 per cent of the US elderly pay from US$600 to $1200 out – of pocket per year for drugs, and more than 16 per cent pay over US$1200 per year. In contrast, under five per cent of the elderly in Australia, Canada and New Zealand (with PBS-like subsidy schemes) face prescription drugs costs over US$1200 (Schoen *et al*. 2000, p. 13). High drug costs have been shown to be associated with difficulties meeting basic living expenses such as food, housing and transportation. Of those US elderly with high out-of-pocket drug costs, 29 per cent had problems meeting daily living expenses (Commonwealth Fund 2000, p. 3). Similarly, a US Senate report found that despite safety nets, out-of-pocket pharmaceutical expenditures and

unregulated pricing meant that five million older Americans were forced to choose between buying food and buying medicine (USSCA 1992).

3.3 Price discrimination in a deregulated pharmaceutical market

Experience in the US indicates that a free market system of price determination is likely to lead to price discrimination. Price discrimination refers to the sale of goods or services to different buyers at different prices when the price differences are not justified by the differences in the cost of producing the product for the different buyers. Price discrimination is most profitable for a company when consumers can be easily divided into groups that have significantly different price 'elasticities'. Price elasticity refers to the sensitivity of quantity demanded to changes in price. Price discrimination has been legal in Australia since amendments to the *Trade Practice Act (1974)* came into force in 1995.

A report commissioned by US Congressman Henry Waxman, found that the deregulation of pharmaceutical pricing in the US led to manufacturers exploiting those populations with the least elastic demand profiles for medications (USHoR 1999). The elderly are the demographic group whose demand for pharmaceuticals is least sensitive to price rises because most of the medicines required by the elderly are essential for their health and well-being. Where lifesaving products are concerned patients will even forgo necessities in order to purchase their medicines.

Clearly if markets are allowed to determine the price of medicines, then price discrimination is likely in Australia. As the Waxman report revealed the price senior citizens paid for the five drugs investigated was on average 134 per cent higher than the price paid by the drug companies' most favoured customers, large health management organizations (USHoR 1999, p. i). Table 11 provides a summary of these results.

Table 11 Price discrimination practised in the deregulated pharmaceutical market in the US

Drug	Use	Prices for favoured customers	Average price for seniors	Differential $	Differential %
Zocor	Cholesterol	$27.00	$107.66	$80.66	29%
Norvasc	Blood pressure	$59.71	$118.96	$59.25	99%
Prilosec	Ulcers	$59.10	$117.56	$58.46	99%
Procardia XL	Heart	$68.35	$133.22	$64.87	95%
Zoloft	Depression	$125.73	$223.61	$97.88	78%

Source: USHoR (1999)

4. The politics of the PBS

4.1 Why would the Government agree to the deregulation of the PBS?

This paper examines the dangers associated with a move away from the current PBS system, with its strong emphasis on cost control, towards a more deregulated system with increased emphasis on higher co-payments to reduce demand. Evidence presented concerning the experience in the US and Singapore suggests that a movement towards a US-style system will not reduce the cost to society of necessary pharmaceuticals.

Why then would the Australian Government, in negotiating an Australia-US FTA, consider reducing the effectiveness of the price controls that underpin the PBS? Any attempt to answer such a question must consider the distinction between the cost of pharmaceuticals to society and their cost to the Commonwealth budget. Cost shifting in the Australian health system is well understood and widely practised by all levels of government.[4] Deregulation of pharmaceutical pricing in Australia can best be understood as a form of cost shifting from the Commonwealth Government to individuals within society.

The Government has already attempted to shift a number of pharmaceutical and other medical expenses from the Commonwealth to individuals. For example, the proposal in the 2002 Commonwealth budget to increase the co-payment made by individuals purchasing prescription medicine was an explicit attempt to reduce the cost to the Commonwealth by increasing the cost to individuals. More recently the Commonwealth Government has announced its intention to entrench further the use of co-payments for visits to GPs.

The desirability of cost shifting must be assessed in terms of efficiency and equity. The previous sections have shown that the shifting of pharmaceutical costs from the Commonwealth is neither efficient nor equitable. In terms of efficiency, Australians will be collectively disadvantaged if the Commonwealth Government relinquishes its strong bargaining position *vis a vis* the international drug companies. There is no doubt that individuals, or even private health insurers, will be unable to negotiate the same low prices for necessary medicines as are currently achieved by the Government. Cost shifting in relation to pharmaceuticals will further reduce the equity of the current system, with severe implications for the affordability of health care for the chronically sick and the elderly.

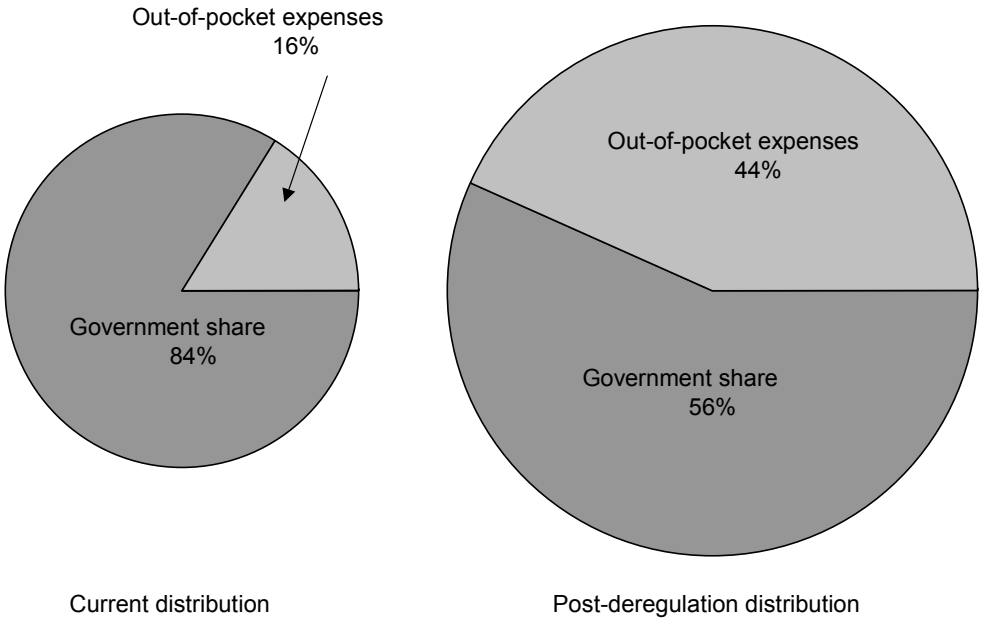
There does not appear to be any major financial or equity benefit associated with changing the PBS in the manner sought by pharmaceutical manufacturers. If individuals are able to afford higher co-payments for their medicines then they can afford to pay the same amount in taxes to fund the current arrangements. Given that the drug companies themselves concede that Australian taxpayers will pay at least $1 billion more each year for their medicines, moving away from the current system could only achieve benefits to the budget at a cost to society as a whole. However, given the extent of the increases in the co-payment that would be necessary to fund even a $1 billion dollar rise in the

[4] For a discussion see Senate Community Affairs References Committee (2000)

costs of pharmaceuticals, it is possible that at least some of the costs of the FTA will be borne by the Commonwealth.

Figure 10 shows the result of cost shifting after deregulation of the PBS assuming that pharmaceutical consumers pay the entire increased cost. The post-deregulation distribution is based on the 48 per cent increase in the cost of medicines (Productivity Commission 2001). Government outlays on pharmaceuticals are assumed to remain constant.

Figure 10 The distribution of PBS costs before and after deregulation



Source: calculation based on DoHA (2002c) and Productivity Commission (2001)

4.2 What does Australia have to gain from entering an FTA?

Free trade agreements are voluntary agreements. At the end of negotiations, an FTA will only be implemented if both parties agree that the outcome is desirable. Bargaining power in such a situation is therefore a function of which party feels they need the agreement more. Given the relative size of the US and Australian economies, there is no doubt that increased trade resulting from increased access to the US is more valuable to Australia, as a percentage of GDP, than free access to Australia is to the US (Ranald and Southalan 2003).

The main advantages of negotiating an FTA with the US would be likely to flow to sections of the Australian agriculture industry which could expand if the US market were opened up. While the benefits of such expansion would be captured by a small percentage of the Australian economy, the costs of deregulating the PBS, along with a

range of other likely concessions, would be borne by all Australians. It is also important to note that even some sections of the Australian agriculture industry will possibly suffer damage as Australia's strict quarantine restrictions are likely to be challenged along with existing regulations concerning genetically modified crops (Zoellick 2002).

Australia has been let down previously by the US in relation to the liberalisation of trade. Last year when the US Farm Bill was announced, Australia's Minister for Agriculture described the moves by the US to protect its farmers with massive subsidies at great cost to our own as being 'betrayed by a friend' (Phillips 2002). Similarly, as the ABC reported last year in relation to the above incident:

> There's been so much tough talk from Australia over the unfairness of the US farm subsidies and yet when Mr. Howard had the rare opportunity to tackle Congress directly on it, the toughest word he could come up with was disappointed. He basically let the US off the hook (Phillips 2002).

While the economic benefits of an FTA continue to be debated, there appears to be no doubt that they are unlikely to be large. Furthermore, in negotiating an FTA, the social and environmental costs of the deal also need to be included in any estimation of the public interest. No such analysis has been provided by the Commonwealth Government.

Again, the question of why the Government would pursue such a deal once again arises. It is possible that the Australian Government rates the significance of achieving an FTA with the US highly as an end in itself. Alternatively, it must be remembered that the Minister for Trade, the Hon. Mark Vaile, is a member of the National Party which, according to the Party's website:

> is a staunch advocate for the nation's wealth generating rural and resource industries. It was born out of farm organisations and still places priority on agricultural and trade policies (National Party 2003).

While the Trade Minister may have been elected to represent the interests of primary producers, it is the role of Government to make decisions that are in the national interest.

A final motive for winding back the PBS may be the Prime Minister's lack of faith in publicly funded healthcare. John Howard has repeatedly defended his Government's decision to provide billions of dollars in subsidies to the private health insurance industry while the public system faces increasing strain. In 1987, as Leader of the Opposition, he said:

> Everybody knows that one of the great disasters…has been Medicare. It's raped the poor in this country (quoted in Beazley 2000).

5. Conclusion

The PBS is an effective means of ensuring that all Australians have access to essential pharmaceuticals. The Australia-US FTA negotiations are applying a new source of pressure on the Australian Government to reduce the effectiveness of the PBS in controlling pharmaceutical prices. If US pharmaceutical interests and their Australian subsidiaries succeed in their bid to use their close ties to the Bush Administration and Howard Government to force the inclusion of the PBS in the FTA negotiations, the adverse consequences have the potential to be significant. In summary the consequences are likely to include:

- an increase in the national cost of pharmaceuticals of at least $1 billion and up to $2.4 billion;
- A surge in direct to consumer advertising aimed at inducing patient demand for more expensive brand named medicines, as well as the substitution of pills for more appropriate lifestyle therapies;
- The erosion of safety nets to the elderly, the sick and the poor due to an unavoidable shift to increased co-payments for prescription drugs; and
- a net transfer of wealth from Australians to international pharmaceutical manufacturers as a result of price rises.

The only significant potential benefit is a possible decrease in the lag time for accessing some new therapies that will then be available only to those who can afford them.

Australia's unique and effective PBS is under threat from the creation of a free trade agreement between Australia and the US. The Australian Government has stated that its objective in negotiating an FTA is to increase the capacity for Australian agricultural exporters to sell their products into the US market. In order to achieve this goal it has refused to rule out changes to the PBS which would result in increases in the cost of pharmaceuticals to Australian citizens.

The US government has already received submissions from the US pharmaceutical companies calling for the deregulation of drug pricing in Australia. The body representing the interests of the US pharmaceuticals industry in Australia, Medicines Australia, has referred to the impact of the PBS on the price paid for medicines by Australians as 'insidious'. Medicines Australia also provided alternative policy approaches to the Commonwealth Government based on increasing the out-of-pocket expenses incurred by those who are ill.

There is, therefore, no doubt that the Australian Government will come under pressure to reduce the effectiveness of the current PBS in controlling drug prices in the FTA negotiations with the US. Under such circumstances it is important that the costs of deregulating the pricing of pharmaceuticals in Australia are widely understood.

Reductions in the effectiveness of the PBS, whether through an FTA or other domestic processes, have the capacity to deliver windfall gains to the Commonwealth budget and

pharmaceutical companies at the expense of Australian citizens who will be required to pay more in out-of-pocket expenses. The fact that even the pharmaceutical lobby concedes that Australian consumers will pay more than the government will save is conclusive evidence that watering down the PBS is not in Australia's national interest.

Access to affordable pharmaceuticals is an essential component of Australia's health system in addition to providing an important plank on which equity is delivered in Australia. Movement toward a system whereby the chronically ill and the elderly are asked to pay higher prices in order to fund a greater return to pharmaceutical manufacturers is undesirable from both a health policy and an equity point of view.

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