

Australia-United States Free Trade Agreement and the Australian Pharmaceutical Benefits Scheme

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INTRODUCTION

This Case Study examines, with particular reference to the Australian Pharmaceutical Benefits Scheme (PBS), the events that occurred during the negotiation of the Australia-United States Free Trade Agreement (FTA) in 2003 and early 2004. The inclusion of the PBS in the FTA was a source of considerable concern in Australia due to its potential impact on health, and was a sticking point in negotiations.

Following brief descriptions of the PBS and the relationship between drug companies and the PBS, I outline in roughly chronological order some of the significant developments in the negotiations from a public health viewpoint. I also analyze the framing of the negotiations by the United States and Australian governments and the lack of transparency and public accountability with which the negotiations took place. I argue that trade negotiations, like the FTA, can have important health consequences; as such, public health advocates must become more active participants in the negotiations process.

This Case Study tells a story of process, not outcomes. In the telling I wish to stimulate consideration of the role public health workers can play in international trade negotiations, an arena in which they have not traditionally been much involved, but one that will assume increasing importance for the health of both individuals and nations.

AUSTRALIAN PHARMACEUTICAL BENEFITS SCHEME (PBS)

The Australian federal government¹ established the PBS in 1948 to

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1. Australia—in the bottom left-hand corner of the Pacific, with a population of twenty

ensure that all Australians would be able to afford the increasingly effective, yet more expensive, therapeutic drugs that were becoming available. Since 1948 the range of drugs included in the PBS has expanded, the cost to the government has increased, and the mechanisms by which drugs are assessed for inclusion in the scheme have changed. Nonetheless, the PBS has retained its basic characteristics over the last six decades. The following is a brief review of the services the PBS now provides:

- A federal government subsidy for approximately 600 prescribed medications—in approximately 2600 different forms, strengths and brands—for all Australians.² Nearly eighty percent of all prescription medicines available at pharmacies are included.³ The total government contribution is uncapped and currently totals around \$4.5 billion Australian dollars (AUD) per year.⁴
- Fixed out-of-pocket expenses for patients. Most members of the public pay up to AUD\$24 per prescription and approved pension cardholders pay AUD\$4 per prescription.⁵ Although it varies from drug to drug, overall for every dollar paid by a patient, the PBS contributes five.⁶
- A financial safety net for chronically sick people who require multiple prescriptions. The PBS covers all out-of-pocket expenses in excess of AUD\$200 per year for pensioners and reduces the cost per prescription to AUD\$4 for non-pensioners

million—has a federal-state system of government similar to the United States. Under the Australian Constitution, states have primary responsibility for the provision of health services, but over the years the federal government has acquired many responsibilities by funding nation-wide programs. For further information on shared health programming responsibilities in Australia, see, for example, John McMillan, *The Constitutional Power of the Commonwealth in Public Health*, in PUBLIC HEALTH LAW IN AUSTRALIA – NEW PERSPECTIVES 105-37 (1998), available at <http://www.health.gov.au/pubhlth/publicat/document/law2.pdf>; RICHARD SCOTTON & CHRISTINE R. MACDONALD, THE MAKING OF MEDIBANK (Univ. of N.S.W. School of Health Servs. Mgmt., Australian Studies in Health Service Admin. No. 76, 1993).

2. Austl. Dep't of Health & Ageing, General Public: Pharmaceutical Benefits Scheme, at <http://www.health.gov.au/pbs> (last visited Mar. 1, 2004).

3. Austl. Dep't of Health & Ageing, About the PBS, at <http://www.health.gov.au/pbs/general/aboutus.htm> (last modified Dec. 24, 2003).

4. *Id.* At the time of publication, 1 AUD = USD \$0.76. This value was determined using The Universal Currency Converter, at <http://www.xe.com/ucc/>.

5. Austl. Dep't of Health & Ageing, *supra* note 3.

6. *Id.*

- once their out-of-pocket expenses exceed AUD\$700 per year.⁷
- Strict government controls over which drugs are included in the scheme, and the medical conditions for which they are approved. All applications for a drug to be included in the PBS are carefully assessed by government appointed committees. New drugs are included only if they demonstrate a therapeutic benefit over existing PBS-listed drugs and an economic benefit for the government (e.g., a generic preparation of an existing PBS-listed patented drug).⁸ Not all drugs that fulfill the first criterion are included in the PBS, however. Although there is no explicit threshold, drugs for which the additional cost per life-year gained is less than AUD\$42,000 (1998/99 values) tend to be approved; drugs with an additional cost per life-year gained over AUD\$76,000 tend not to be approved.⁹
 - Close management of government payments for drugs included in the PBS. The price the government will pay for a drug is based on therapeutic worth (i.e., its usefulness to the patient compared with other available drugs), not on how much it cost the drug company to develop and produce the drug. If evidence demonstrates that a new drug is no better for patients than an existing drug, the government will pay the producer of the new drug only what it pays the producer of the existing drug.¹⁰ This is a variant on the reference pricing systems utilized by many governments throughout the world. The government's bargaining position is, of course, strengthened by its near monopsony.

The result is that Australia has one of the cheapest drug bills in the developed world: Compared with the United States, the PBS saves Australia about AUD\$1-2.5 billion per year.¹¹ Yet, Australians still have access to the

7. Austl. Dep't of Health & Ageing, *Frequently Asked Questions*, at <http://www.health.gov.au/pbs/general/faq.htm#safety2>.

8. K. LOKUGE & RICHARD DENNISS, *THE AUSTL. INST., TRADING IN OUR HEALTH SYSTEM: THE IMPACT OF THE AUSTRALIA-US FREE TRADE AGREEMENT ON THE PHARMACEUTICAL BENEFITS SCHEME* vii-viii (The Austl. Inst. Discussion Paper, No. 55, 2003), http://www.tai.org.au/Publications_Files/DP_Files/DP55suma.pdf.

9. Bethan George et al., *Cost-Effectiveness Analysis and the Consistency of Decision Making: Evidence from Pharmaceutical Reimbursement in Australia (1991 to 1996)*, 19 *PHARMACOECONOMICS* 1103, 1103-1109 (2001).

10. LOKUGE & DENNISS, *supra* note 8, at 9, 22.

11. *See id.* Given the exchange rate at the time of publication, Australians save between \$765,000,000 and \$1,835,000,000 annually on drugs costs compared with the United States.

newest drugs (provided evidence demonstrates that they are safe and effective) in a timely fashion and at a price that most patients and the country as a whole can afford. Advocates of the PBS claim that it delivers high quality health care, good money value, efficiency and equity—a powerful and unusual combination of attributes.¹² Over the last decade the cost of the PBS has increased by approximately fifteen percent per year, the number of prescriptions has increased by five percent per year, and the price per prescription has increased by nine percent per year.¹³ By world standards the PBS's performance in controlling drug costs has been very impressive, and it has many international admirers.¹⁴

DRUG COMPANIES AND THE PBS

Not surprisingly, drug manufacturers enjoy the stability and reliability offered by government purchasing but do not appreciate the strict governmental controls placed on them by the PBS. Drug companies have three major criticisms. First, they argue that because the PBS uses very strict cost-efficacy data to determine drug availability and pricing, it unfairly restrains trade by limiting companies' freedom to charge whatever the market will pay.¹⁵ Second, drug companies complain that the PBS does not allow them to recoup their immense investments in research and development (R&D), and hence that Australians are freeloading on patients in countries with higher drug prices, such as the United States.¹⁶ Third, they call for consumers, including socially disadvantaged ones, to

12. See, e.g., PUB. HEALTH ASS'N OF AUSTRALIA, PHARMACEUTICAL BENEFITS SCHEME (PBS) AND THE AUSTRALIA:UNITED STATES OF AMERICA FREE TRADE AGREEMENT (FTA) POLICY, 2003 (adopted 2003), available at <http://www.phaa.net.au/policy/freetrade.htm>; AUSTRALIAN FAIR TRADE & INVESTMENT NETWORK (AFTINET), TRADING AUSTRALIA AWAY? (2003), <http://www.aftinet.org.au/campaigns/USFTALeaflet.May03.pdf>; Peter Sainsbury, *A Bitter Pill*, 16 RADIUS 5 (2003), available at http://www.mga.usyd.edu.au/radius/Radius_Vol%2016%20no%201.pdf.

13. LOKUGE & DENNISS, *supra* note 8.

14. PRODUCTIVITY COMM'N, INTERNATIONAL PHARMACEUTICAL PRICE DIFFERENCES (2001); NATIONAL CENTRE FOR EPIDEMIOLOGY AND POPULATION HEALTH, THE EFFECTS OF THE GENERAL AGREEMENT ON TRADE IN SERVICES ON AUSTRALIAN POPULATION HEALTH: SUBMISSION TO THE SENATE INQUIRY INTO THE GENERAL AGREEMENT ON TRADE IN SERVICES (GATS) (2003), http://nceph.anu.edu.au/Publications/pdfs/Senate_GATS_inquiry_submission.pdf.

15. MEDICINES AUSTRALIA, A PRESCRIPTION FOR THE FUTURE HEALTH OF AUSTRALIA: SUBMISSION TO THE INTER-DEPARTMENTAL COMMITTEE PREPARING A REPORT ON THE EFFECTIVENESS OF THE PBS (2002).

16. *Id.*

assume greater responsibility for the costs of medications.¹⁷

Essentially, drug companies desire greater freedom to sell their products in Australia at whatever price the market will support, preferably while maintaining a government program that guarantees both a market for their drugs and a combination of reliable payers. Perhaps more significantly, drug companies, who are mostly multinational conglomerates with large financial interests in the United States, have a strong interest in political developments there. Efforts to undermine the PBS can also be seen as an attempt to discourage U.S. legislation allowing the Centers for Medicare and Medicaid Services to implement a similar program, with negotiation of large price discounts domestically on behalf of the Centers' forty million beneficiaries.¹⁸ As a result of these dual motivations, drug companies lobbied the Australian government and threatened legal action to undermine the PBS before the FTA negotiations began.¹⁹

It is worth noting that it is bigger profits—not survival—that the drug companies are fighting for. In the United States the pharmaceutical industry has provided the highest return on investment, among industries, every year for the last ten years²⁰ and drug companies feature prominently among the largest and the most profitable companies worldwide.²¹ Regarding drug companies' R&D costs, both their marketing and advertising expenses (approximately twenty-seven percent of revenue for the nine major U.S. drug companies) and their profits (approximately eighteen percent) exceed what they pay in R&D (approximately eleven percent).²²

NEGOTIATING THE AUSTRALIA-UNITED STATES FREE TRADE AGREEMENT

The free trade agreement between Australia and the United States was finalized in February 2004 following a year of negotiations. Early in 2003 public health observers in Australia, already made wary by discussions about multilateral trade agreements, were alerted by media reports to the

17. *Id.*

18. Sheryl Gay Stolberg & Gardiner Harris, *Industry Fights To Put Imprint on Drug Bill*, N.Y. TIMES, Sept. 5, 2003, at A2 (reprinted as *Donate or Else, Drug Companies Told Staff* in the SYDNEY MORNING HERALD, Sept. 9, 2003, available at <http://www.smh.com.au/articles/2003/09/05/1062549020461.html?from=storyrhs>).

19. LOKUGE & DENNISS, *supra* note 8.

20. *See id.*

21. Donald L. Barlett & James B. Steele, *Why We Pay so Much for Drugs*, TIME, Feb. 2, 2004, at 44.

22. LOKUGE & DENNISS, *supra* note 8.

possible inclusion of the PBS in the Australia-United States bilateral FTA. Several elements of these reports provoked concern. First, the U.S. drug industry testified during U.S. public hearings into the FTA about the allegedly low prices paid for new drugs in Australia and identified the PBS as a target for inclusion in the FTA.²³ Second, U.S. negotiators pushed for greater transparency in the evaluation of drugs for inclusion in the PBS; an appeals mechanism for denied applications; and changes to the pricing mechanisms of the PBS (including changes to the reference pricing system and adjustments for inflation).²⁴ Third, the U.S. drug companies' trade association, the Pharmaceutical Research and Manufacturers of America (PhRMA), budgeted at least USD\$150 million per year to lobby U.S. and foreign governments to fight price controls and protect patents.²⁵

These revelations prompted opposition political parties and those concerned about public health in Australia to question the government about the inclusion of the PBS in the FTA negotiations.²⁶ The responses from the Australian government were evasive, failing to confirm or deny whether the PBS would be discussed as part of the negotiations.²⁷

It is of particular interest that opposition to inclusion of the PBS in the FTA did not come solely from the Australian side. Several U.S. politicians were unhappy about the attempt by the United States to influence the PBS, and seven wrote to President Bush in October 2003 praising the PBS and urging the President to "indicate to the Australians that the U.S. has no

23. Tom Allard, *US Drug Companies Cry Poor over PBS*, SYDNEY MORNING HERALD, Jan. 17, 2003, at 4.

24. Morgan Mellish, *US Drug Firms Push for Changes to PBS*, AUSTRALIAN FIN. REV., Mar. 3, 2003, at 3.

25. Robert Pear, *Drug Companies Increase Spending on Efforts to Lobby Congress and Governments*, N.Y. TIMES, June 1, 2003, at 33.

26. John Garnaut, *No Free Trade Without Open Markets: Vaile to US*, SYDNEY MORNING HERALD, Mar. 4, 2003, at 4; Matt Wade & John Garnaut, *Drug Price Fears Over Trade Deal*, SYDNEY MORNING HERALD, Mar. 18, 2003, at 5; Press Release, Craig Emerson & Stephen Smith, Keep PBS Out of US FTA Negotiations (Mar. 19, 2003), <http://craigemersonmp.com/mediatm?id=410&sv=offset=14&0=>.

27. Many media outlets documented the government's conflicting statements on this issue. See, e.g., Garnaut, *supra* note 26; Emerson & Smith, *supra* note 26; Press Release, The Austl. Inst., Vaile Attempts To Cover Up US FTA Intentions (May 19, 2003), http://www.tai.org.au/MediaReleases_Files/MediaReleases/PRFTAand%20Vaile.pdf; Media Briefing, Stephen Deady & Ralph Ives, Up US FTA Intentions Austl. Dep't of Foreign Affairs & Trade, The First Round (17-21 March) of Free Trade Agreement Negotiations Between Australia and the United States (Mar. 21, 2003), http://www.dfat.gov.au/media/transcripts/2003/030321_fta_brief.html.

interest in negotiating any changes to the Australian Pharmaceutical Benefits Scheme that would hamper its ability to conduct and review comparative effectiveness and cost effectiveness studies on pharmaceuticals.”²⁸

In January 2004, nine senior Democrats in the House of Representatives wrote to President Bush with similar concerns.²⁹ Anxious to protect the U.S. Veterans Administration, Indian Health Service and Department of Defense drug purchasing arrangements, the Democrats also sought reassurance that the FTA would not change the pricing structure of U.S. government procurement programs for drugs.³⁰

As the debate in Australia continued throughout 2003 and January 2004, non-government public health sources provided careful analyses of the possible health effects of the inclusion of the PBS in the FTA;³¹ made submissions to government entities;³² issued press releases; worked with others to focus political, media and public attention on the FTA negotiations;³³ and maintained an active network of concerned individuals and organizations. I personally spoke at several public meetings, some organized by concerned citizens’ groups, gave many media interviews and wrote several short articles for newspapers and small-scale publications.³⁴ With relatively limited resources available, and an uncooperative (and evasive) government, it is difficult to see what else public health workers could have done during this period to protect the PBS.

28. Leigh Sales, *PBS a Stumbling Block in US-Aust Free Trade Talks* (ABC radio broadcast, Jan. 14, 2004), available at <http://www.abc.net.au/am/content/2004/s1025409.htm>; Press Release, Rep. Tom Allen, Statement on Completion of the U.S.-Australia Free Trade Agreement (Feb. 10, 2004), <http://tomallen.house.gov/printer.asp?contentID=1224>.

29. *US Dems Express FTA Drug Fears*, SYDNEY MORNING HERALD, Jan. 19, 2004, available at <http://www.smh.com.au/articles/2004/01/19/1074360692066.html>.

30. Letter from Nancy Pelosi et al., to George W. Bush (Jan. 2004) (on file with author).

31. See, e.g., LOKUGE & DENNISS, *supra* note 8; BUDDHIMA LOKUGE ET AL., A BACKDOOR TO HIGHER MEDICINE PRICES? INTELLECTUAL PROPERTY AND THE AUSTRALIA-US FREE TRADE AGREEMENT (Nov. 2003), available at http://www.tai.org.au/WhatsNew_Files/WhatsNew/Patents.pdf.

32. TRACY SCHRADER, DOCTORS’ REFORM SOCIETY, HEALTH IMPLICATIONS OF THE PROPOSED FREE TRADE AGREEMENT BETWEEN AUSTRALIA AND THE UNITED STATES (Jan. 2003), available at http://www.drs.org.au/new_doctor/78/Schrader_FTA_78.htm.

33. AUSTRALIAN FAIR TRADE & INVESTMENT NETWORK, *supra* note 12.

34. Sainsbury, *supra* note 12; Peter Sainsbury, *To Prevent Medicare Hit, Senators Must Not Fall for the Myths*, SYDNEY MORNING HERALD, Jul. 23, 2003, at 17; Peter Sainsbury, *The Crisis in Health(care)*, HOSPITAL&HEALTHCARE, May 2003, at 10.

SPINNING THE AUSTRALIA-UNITED STATES FREE TRADE AGREEMENT

The FTA was finalized on February 8, 2004, although the full text was not made available until March 4, 2004. In the meantime, both governments placed summaries of the agreement on the websites of their respective trade departments. Not surprisingly, each government sought to put a positive spin on the agreement for their own interest groups and emphasized the concessions they had won and the places where they had stood firm. Comparing what each said about the PBS is interesting. The U.S. government highlighted:³⁵

- The shared recognition of the importance of innovative pharmaceuticals in health care, R&D in the pharmaceutical industry and the protection of intellectual property; the need to promote timely and affordable access to innovative pharmaceuticals through transparent, expeditious and accountable procedures; and the need to recognize the importance of innovative pharmaceuticals through procedures that value their objectively demonstrated therapeutic significance;
- The improved transparency and accountability in the PBS that will flow from the establishment of an independent process to review determinations of product listings;
- The establishment of a joint Medicines Working Group to promote discussions on emerging health care policy issues;
- The quicker availability of innovative medical products that will arise from collaboration between the U.S. Food and Drug Administration and the Australian Therapeutic Goods Administration;
- The stronger protections for patents and trade secrets that will arise from, for instance, the extension of patent terms to compensate for delays in granting patents and the provision of notice to the patent holder when the validity of a drug patent is to be challenged.

The Australian government meanwhile emphasized:³⁶

35. Press Release, Office of the U.S. Trade Representative, U.S. and Australia Complete Free Trade Agreement (Feb. 8, 2004), http://www.ustr.gov/Document_Library/Press_Releases/2004/February/U.S._Australia_Complete_Free_Trade_Agreement.html.

36. MARK VAILE, FREE TRADE AGREEMENT WITH THE UNITED STATES (Feb. 8, 2004), <http://www.dfat.gov.au/trade/negotiations/us.html>.

- Maintaining accessibility to affordable medicines under the PBS and the fulfillment of the government's promise that the price of drugs will not increase as a result of the FTA;
- Improving public understanding of the PBS system and faster access to subsidies for new drugs that will arise from improvements to the transparency and timeliness of PBS processes;
- Increasing opportunities for companies seeking listing of new drugs to have input to the process;
- Reinforcing Australia's existing intellectual property protection framework for drugs, and the benefits that will arise from aligning Australia's intellectual property regime with that of the world's largest intellectual property market.

No one will be surprised that each government promoted aspects and interpretations of the agreement that mollified the groups that each was seeking to please. Nor is it surprising that the two governments publicly presented their own interpretations of the FTA for a month before the actual wording of the agreement was released. The delay and the spin were frustrating for public health advocates, but the ready availability of this information on government websites permitted revealing comparisons to be made and facilitated more rapid critical appraisal of the full text when it became available.

WHAT THE FTA ACTUALLY MEANS FOR THE PBS

The full text of the FTA³⁷ was released on March 4, 2004, but it added little detail to what had already been made public. Given the conflicting accounts of the FTA presented by Australia and the United States, and the differing interpretations of the sections covering the PBS, it is clear that the Australian government is trying to pull the wool over someone's eyes. But, is it the U.S. negotiating team and the pharmaceutical industry, or is it the Australian public? Has the Australian negotiating team managed to conjure up forms of words and agree to bureaucratic changes that will make no substantive difference to the PBS (in some cases because the arrangements already exist) and thus provide no real gains for drug companies? Or are the changes to the mechanisms of the PBS ultimately going to increase drug prices for sick Australians? Will this make it difficult for poorer Australians to afford the medications they need? Will equity in

37. OFFICE OF THE U.S. TRADE REPRESENTATIVE, UNITED STATES-AUSTRALIA FREE TRADE AGREEMENT (Mar. 1, 2004), <http://www.ustr.gov/new/fta/Australia/text/index.htm>.

Australia's health care system be reduced?

Immediately after March 4, support for all these views could be found in the Australian media. Government spokespeople provided reassurances that nothing in the FTA would threaten the structure of the PBS or lead to increased drug prices;³⁸ political commentators and public health workers predicted dire consequences for the price of drugs in Australia;³⁹ and drug company representatives expressed delight with the FTA and its implications for prices, profits and investment.⁴⁰

THE FTA AND THE DEMOCRATIC PROCESS

Ironically, throughout much of the negotiation process, Australian observers were able to obtain more information from American than Australian sources,⁴¹ and in general the U.S. side of the negotiations was more open to public scrutiny. Indeed, it was easy to form the impression in Australia that the government would have been happier if people had found the proposed FTA and the negotiation process too difficult and complex to comprehend and had simply left it to the government to sort out. Additionally, there is no requirement in Australia for the whole FTA to be placed before the Australian parliament for debate and ratification, although some of the specific tariff barrier changes do need parliamentary approval.

During 2003 and early 2004, the efforts of individuals and groups who were concerned about possible harmful effects of the FTA in Australia did, however, ensure that the Australian government was aware that the wording of the agreement would be closely scrutinized. Also, in January 2004 the federal opposition announced that it would refer the FTA, once finalized, to a Senate Select Committee for a public inquiry and "thorough examination."⁴² In an unsuccessful attempt to forestall this parliamentary delaying tactic, which ran the risk of producing much adverse publicity

38. Mark Metherill et al., *Drug Scheme at the Forefront of Trade Scrutiny*, SYDNEY MORNING HERALD, Mar. 5, 2004, at 6; Mark Davis, *PBS Appeals, Cosmetic or Not?*, AUSTRALIAN FIN. REV., Mar. 5, 2004, at 6.

39. Alan Ramsey, *Howard's Labours Are Slipping Away*, SYDNEY MORNING HERALD, Mar. 6, 2004, at 37; Lisa Allen, *Drugs Appeal To Be Burden*, AUSTRALIAN FIN. REV., Mar. 5, 2004, at 7.

40. Allen, *supra* note 39; Davis, *supra* note 36.

41. American sources that were both informative and readily available to the Australian public included newspapers, the PhRMA website, U.S. negotiators' media conferences, and U.S. government hearings. See, e.g., Barlett & Steele, *supra* note 21.

42. Press Release, Mark Latham & Stephen Conroy, Labor To Refer Australia-US FTA to Senate Committee (Jan. 27, 2004) (on file with author).

about the FTA, in March 2004 Minister Vaile referred the agreement to the government-controlled Joint Standing Committee on Treaties for a public inquiry and report to Parliament.⁴³ Thus, at the time of publication, Australia has two parliamentary inquiries into the FTA and I do not think many people will be surprised if they reach markedly different conclusions. The democratic process and the FTA (not to mention the public purse) might all have benefited more from just one public enquiry twelve to eighteen months earlier.

One might ask why the Australian government, which itself considers the PBS to be one of the best systems of its kind in the world,⁴⁴ was so willing to allow the scheme to be placed on the negotiating table. One can only speculate, but the current Australian (conservative) government has consistently promoted increased private provision of and increased user payments for health services, rolling back the public sector and decreasing government intervention in industry generally. Those of a Machiavellian disposition might conclude that the government is hoping PBS costs will blow out to such an extent that they can argue that the PBS is no longer financially sustainable and that the only responsible response is to restrict access to it and turn it from a universal program to a welfare based safety net for the poor. Alternatively, or perhaps additionally, the government may have initially hoped that if it made some major concessions on the PBS it would be able to negotiate a better deal on agricultural exports to the United States. Or perhaps the government hoped that a less evidence-based PBS decision-making process would lead to higher drug prices and higher drug company profits and that this would tempt drug companies to increase their investment and production capacity in Australia.

It is also worth noting that several senior advisers to the current Australian government have moved on to senior positions in drug companies.⁴⁵ These links between the government and the industry, and the consequent conflicts of interest, were not made public by either of these groups and are an example of how poor transparency in government processes can create, perhaps unjustified, suspicions about the underlying motivations for government policies.

In yet another twist, despite the FTA as a whole not needing

43. Press Release, Andrew Southcott, Public Inquiry into the Australia-US Free Trade Agreement (Mar. 10, 2004) (on file with author).

44. Austl. Dep't of Health and Ageing, *supra* note 3.

45. Press Release, Pub. Health Ass'n of Austl., Howard Government Plays Mean and Tricky on the PBS in the Australia/US Free Trade Agreement (Mar. 4, 2004), available at http://www.phaa.net.au/Advocacy_Issues/howardgovfta.htm.

parliamentary approval, it is possible that the opposition parties in the Senate will reject the specific tariff barrier changes that do need parliamentary approval and that these relatively few issues will scupper the whole agreement.

LESSONS FOR PUBLIC HEALTH

It is regrettable that in a supposedly democratic nation negotiations which have the potential to (1) increase the price of medications for Australia as a whole and for individual patients, (2) limit the access of many poorer people to essential medications, and (3) damage public health and the broader social infrastructure, have been conducted with such a lack of transparency and public and parliamentary debate.⁴⁶ Governments would, in my opinion, do well to remember that universal suffrage and the opportunity to participate in regular secret ballots are not the only hallmarks of a democratic society. The manner in which even legitimately elected governments conduct the business of government between elections is also an important aspect of democracy. Public health workers have a significant and legitimate part to play in promoting this wider concept of democracy. To do so, however, will require an expansion of public health's traditional role.

With reference to the FTA, this expansion has principally involved:

- Continually monitoring, comparing, analyzing and questioning the information available in, for instance, the media, websites, government publications, press statements and reports of parliamentary proceedings and committees about the content and progress of negotiations;
- Researching and reporting the possible effects on public health of the issues being negotiated. Valid empirical evidence is invaluable in ensuring that politicians, the media and the public are aware of, and care about, the likely health impacts of trade agreements;
- Working with others, inside and outside the health sector, to lobby politicians, mobilize public opinion and keep the matter in the public arena, often over extended periods. For instance, during the FTA negotiations Australian public health workers joined with actors, environmentalists, trades unions and

46. Press Release, Pub. Health Ass'n of Austl., *Howard Should Come Clean on the Pharmaceutical Benefits Scheme* (Dec. 3, 2003), *available at* http://www.phaa.net.au/Advocacy_Issues/howardpharmaceutical.htm.

welfare groups, all of who were concerned about the effects of the FTA on their interests, to prepare analyses, organize public meetings and issue press releases;

- Ensuring that politicians knew that the negotiations were being closely monitored, and that the outcomes would produce benefits and harms, winners and losers, and possibly electoral consequences.

It may be years before the effects of the FTA on the PBS and the Australian drug industry become clear, as indeed it may be years before any conclusions can be reached about whether the FTA has been beneficial for Australia overall. It is also unclear whether the efforts of consumer groups, public health activists, health professionals, opposition political parties, trades unions and public interest groups throughout 2003 to keep the PBS in the spotlight and try to prevent the government trading away the PBS had any effect. And it remains uncertain whether, as a tactic to make the deal unacceptable to the United States, the opposition parties in the Senate will reject those aspects of the FTA that need parliamentary approval.

Three things are clear, however. First, that the drug industry in the United States and Australia saw the FTA as an opportunity to undermine the evidence-based, strict and effective procedures underpinning the PBS. Second, that national and international democratic processes are intimately connected to public health. Third, that public health workers cannot limit their attention to epidemiological method, social theory and academic publication. Those who are concerned about public health (the health of the public, I mean here, not the discipline of study) must also maintain a vigilant eye on the whole of society, glean information from all sorts of sources, cherish values as much as evidence, develop a keen understanding of international affairs, become skilled observers of bureaucratic processes, be prepared to involve themselves in political lobbying and develop methods to monitor the effects of instruments of government such as the FTA. And whatever the gross effects of any policy or action, public health workers must always ask, "Who are the winners, and who are the losers?"

