Barrier to Trade or Barrier to Profit? Why Australia's Pharmaceutical Benefits Scheme Worries U.S. Drug Companies

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INTRODUCTION

Much of the rhetoric that underpins arguments for "free trade" relies on the assertion that free trade agreements between nations are "win–win" arrangements. That is, it focuses on the textbook conclusion that by reducing trade barriers the total volume of goods and services available for consumption will increase and that, as a result, people in participating countries will likely benefit. In reality, free trade agreements are about winners and losers. Individual industries use their political influence to fight for or to defend their domestic or international profitability. For example, in the recently concluded negotiations of a free trade agreement between the United States and Australia, U.S. sugar farmers succeeded in convincing U.S. negotiators to defend them against increased import competition.[1] The "win–win" rhetoric was further challenged during those same negotiations when U.S. pharmaceutical companies convinced U.S. negotiators to press hard for changes to Australian drug pricing policies that limit pharmaceutical profits.

For more than a year prior to the completion of the United States-Australia Free Trade Agreement (FTA), the U.S. pharmaceutical industry lobby group, PhRMA,[2] and its Australian counterpart, Medicines Australia,[3]

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1. *See, e.g.*, Michael Schroeder, *Sugar Growers Hold Up Push For Free Trade*, WALL ST. J., Feb. 3, 2004, at A13.

2. PhRMA refers to the Pharmaceutical Research and Manufacturers of America. *See Who We Are*, PhRMA, *at* http://www.phrma.org/whoweare/ (last visited Mar. 30, 2004).

mounted a campaign to convince both the Australian public and the U.S. negotiators that the Australian Pharmaceutical Benefits Scheme (PBS) is a barrier to trade. PhRMA and Medicines Australia argued that reform was necessary in order to deliver the "win–win" benefits of free trade to both Australian consumers and U.S. pharmaceutical manufacturers.

However, the changes to the PBS desired by U.S. manufacturers would result in the transfer of between $1.0 and $2.4 billion Australian dollars (AUD) per year in the form of higher medicine prices and profits.[4] Moreover, Australia does not have *any* trade barriers that restrict the sale of pharmaceuticals. Like all developed countries, Australia has requirements to ensure that all pharmaceuticals sold to the public are safe,[5] but these requirements apply equally to drugs developed in Australia or the United States. Australia imposes neither tariffs nor quotas on the importation of pharmaceuticals.

Since the final text of the FTA has not yet been released, we can not fully evaluate the outcome of the pharmaceutical industry's campaign.[6] It appears, however, that Australia has promised to make some changes to the PBS.[7] At the very least, the attack on the PBS provides a compelling example of the way in which free trade arguments are enlisted to undermine social policies that act not as barriers to trade, but to excess profit.

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3. Medicines Australia, *at* http://www.medicinesaustralia.com (last visited May 17, 2004).

4. K. LOKUGE & RICHARD DENNISS, TRADING IN OUR HEALTH SYSTEM? THE IMPACT OF THE AUSTRALIA-US FREE TRADE AGREEMENT ON THE PHARMACEUTICAL BENEFITS SCHEME vii-ix (The Austl. Inst., Discussion Paper, No. 55, 2003), *available at* http://www.tai.org.au/Publications_Files/DP_Files/DP55suma.pdf. At the time of publication,
1 AUD = U.S.$0.76. This value was determined using The Universal Currency Converter, *at* http://www.xe.com/ucc/. Therefore, the changes sought by U.S. pharmaceutical companies would cost Australians between $765,000,000 and $1,835,000,000.

5. *See* AUSTL.DEP'T OF HEALTH & AGEING, 1995 GUIDELINES FOR THE PHARMACEUTICAL INDUSTRY ON PREPARATION OF SUBMISSIONS TO THE PHARMACEUTICAL BENEFITS ADVISORY COMMITTEE, http://www.health.gov.au/pbs/general/pubs/pharmpac/gusubpac.htm (last visited Mar. 30, 2004).

6. Editor's Note: Since the writing of this Case Study, the agreement was signed (on May 18, 2004) and subsequently the final text was released; it is available at http://www.dfat.gov.au/trade/negotiations/us_fta/final-text/index.html (last visited July 1, 2004).

7. *See infra* text accompanying note 34.

THE AUSTRALIAN PBS SYSTEM

The Australian PBS is recognized internationally as a superior pharmaceutical pricing scheme. Professor Richard Laing of Boston University's School of Public Health has stated that "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."[8]

Australia's PBS scheme was established in 1948 in response to concerns that not all Australians could afford vital new medicines such as penicillin.[9] Since then, the scheme has developed as a multibillion dollar subsidy to health consumers—consumers are required to pay a maximum co-payment of AUD$23.10, or AUD$3.70 for low income earners, and the federal government funds any difference between the maximum co-payment and the full price paid to the pharmaceutical company.[10]

Because the Australian federal government is responsible for the difference between the price of the drug paid to the pharmaceutical company and the co-payment made by citizens, it is in the Australian government's interest to minimize the prices paid for medicines. It is the effect of the PBS on prices that is of greatest concern to American drug companies. However, seeking approval for listing on the PBS is only necessary if drug companies, domestic or foreign, wish to avail themselves of the benefits of the Australian subsidy scheme.[11]

For a new drug to be listed on the PBS, approval for its sale must first be obtained from the Therapeutic Goods Administration (TGA), roughly the equivalent of the United States' Food and Drug Administration. In assessing a request for the approval of a new drug the TGA is required to consider, among 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 subsidization on the PBS. It is important to point out that a new drug that has been approved for sale by the TGA can be sold, without subsidy, within Australia. It is only necessary for a pharmaceutical company to seek to have their drug listed on the PBS

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8. *7.30 Report: Australian Benefits Scheme Upsets US Drug Companies* (ABC radio broadcast, Feb. 27, 2001), http://www.abc.net.au/7.30/s252447.htm.

9. LOKUGE & DENNISS, *supra* note 4, at 5; AUSTL. PARLIAMENTARY LIBRARY, THE PHARMACEUTICAL BENEFITS SCHEME—AN OVERVIEW, *at* http://www.aph.gov.au/library/intguide/SP/pbs.htm (last updated Jan. 2, 2003).

10. AUSTL. PARLIAMENTARY LIBRARY, *supra* note 9.

11. *See id.*

if they wish to be eligible for the federal government subsidy.[12]

To ensure that a new drug is eligible for subsidy under the PBS, a supplier must apply to the Pharmaceutical Benefit Advisory Committee (PBAC), a committee of experts whose role it 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.[13] The National Health Act [of] 1953 specifies that the PBAC must consider whether a new drug addresses an unmet medical need or provides a significant improvement in efficacy or a reduction in toxicity over drugs already listed, and is of acceptable cost-effectiveness.[14] This provision is important as it aims to ensure 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) negotiates the price that should be paid to the manufacturer.[15] The PBPA may also stipulate conditions of use, such as restrictions on prescription to specific groups. The Department of Health is then responsible for negotiating a price with the drug supplier. The federal government makes the final decision whether to list the drug at the negotiated price.[16]

U.S. DRUG COMPANIES' CONCERNS WITH AUSTRALIA'S PBS SYSTEM

Pharmaceutical companies are opposed to Australia's approach to price determination, describing the impact of the PBS on the pricing of pharmaceuticals as "insidious."[17] Drug manufacturers in the United States

12. *See id.*

13. Austl. Dep't of Health & Ageing, Pharmaceutical Benefits Advisory Committee, *at* http://www.health.gov.au/pbs/general/listing/committee.htm#pbac (last updated Dec. 16, 2003).

14. AUSTL. DEP'T OF HEALTH & AGEING, GUIDELINES FOR THE PHARMACEUTICAL INDUSTRY ON THE PREPARATION OF SUBMISSIONS TO THE PBAC: PART 1 (Feb. 4, 2003), *at* http://www.health.gov.au/pbs/pharm/pubs/guidelines/part1.htm.

15. AUSTL. PARLIAMENTARY LIBRARY, *supra* note 9.

16. *See* LOKUGE & DENNISS, *supra* note 4, at 8-9.

17. MEDICINES AUSTL., A PRESCRIPTION FOR THE FUTURE HEALTH OF AUSTRALIA: SUBMISSION TO THE INTER-DEPARTMENTAL COMMITTEE PREPARING A REPORT ON THE EFFECTIVENESS OF THE PBS 25 (2002), http://www.medicinesaustralia.com.au/.

have also expressed concern with the "overriding focus on cost-effectiveness" of the PBS and have taken issue with the Australian requirement that "[t]o obtain a premium, the applicant must demonstrate significant clinical advantages over its main comparator and satisfactory cost-effectiveness versus that comparator."[18]

The explicit purpose of Australia's PBS is to ensure that pharmaceuticals are affordable for both individual patients and Australian taxpayers. The use of the government's buying power, combined with expert advice on both efficacy and cost effectiveness, ensures that Australian citizens have access to some of the cheapest prescription drugs in the developed world. Residents of the United States sometimes pay up to ten times as much as Australians for identical pharmaceuticals.[19]

While the PBS is highly effective in lowering the prices paid for pharmaceuticals, it does not, in any way, act as a barrier to trade. As indicated above, the PBS contains no tariff or quota barriers and does not treat domestically designed or manufactured pharmaceuticals any differently from imported substances; moreover, it is not necessary for drugs to be listed on the PBS in order for them to be sold in Australia.[20] It appears that the main concern that pharmaceutical manufacturers have with the Australian PBS scheme is that it is effective in countering both the market power and information asymmetry between customers and suppliers that usually exists within the pharmaceutical industry. Of even greater concern to pharmaceutical companies, it seems, is the possibility that other countries—and even some states within the United States—may implement schemes similar to Australia's.

THE ECONOMICS OF THE PBS

The pharmaceutical industry is characterized by extensive market failure. That is, in the absence of comprehensive government regulation, the industry does not efficiently design, manufacture and distribute pharmaceutical products. The first major form of market failure is due to

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18. PHRMA, 2003 SUBMISSION TO THE US TRADE REPRESENTATIVE (2003), http://www.cptech.org/ip/health/c/australia/phrma-au-2003.html.

19. *See* BUDDHIMA LOKUGE & CLIVE HAMILTON, THE AUSTL. INST., COMPARING DRUG PRICES IN AUSTRALIA AND THE USA: THE IMPLICATIONS OF THE US-AUSTRALIA FREE TRADE AGREEMENT 5 (Jul. 2003), *available at* http://www.tai.org.au/Publications_Files/Papers&Sub_Files/Drug%20comparisons.pdf.

20. It should be noted, however, that the vast majority of prescriptions are covered by the PBS due to the substantial cost advantage that PBS drugs have over non-subsidized medicines.

the "public good" nature of new pharmaceutical substances. Organizations involved in pharmaceutical research and development face substantial private costs associated with developing new products—in the absence of patent protection, pharmaceutical manufacturers could "free ride" on the costly research of an innovator. Thus, without patents, firms would be unwilling to invest sufficient resources in the development of new drugs. In order to create an incentive for the development of new medicines, governments—including the Australian and U.S. governments—provide pharmaceutical companies with the patent right to become a monopoly provider of their new product.

The PBS relies on the monopsony buying power of the Australian government to counter the monopoly selling power possessed by pharmaceutical manufacturers with patent protection. The notion that unregulated market outcomes are efficient, be they within countries or between them, is based on the notion of perfect competition.[21] In a perfectly competitive market, it is assumed that there are large numbers of buyers and sellers and that no buyer or seller has any bargaining power. When a seller has monopoly power, as is the case in the Australian pharmaceutical industry where products are protected from competition by twenty-year patents, providing the buyer with "countervailing bargaining power" will result in a more efficient outcome than if the monopolist is allowed to use its power against a large number of small buyers.[22]

The need to encourage innovation is not the only form of market failure evident in the pharmaceutical industry. Another important form of market failure, one which pharmaceutical companies appear much less concerned about, is the substantial asymmetry that exists between consumers and manufacturers concerning the relative therapeutic worth of alternate forms of treatment. Individuals are simply not best placed to make decisions about which products to purchase: They are unlikely to have either the resources or analytical ability to compare systematically the costs and benefits of a wide range of pharmaceutical and non-pharmaceutical treatments for a given condition. As patents allow pharmaceutical companies to act as monopolists, the profit maximizing strategy for a pharmaceutical company is to take advantage of the lack of information on the part of the consumer and set prices based on "what the market can bear" rather than based on the therapeutic worth of the product or the cost of development. The Australian PBS plays an important role in addressing this information asymmetry.

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21. *See* PAUL A. SAMUELSON & WILLIAM D. NORDHAUS, ECONOMICS 46 (12th ed. 1985).

22. ROBERT S. PINDYCK & DANIEL L. RUBINFELD, MICROECONOMICS 365-66 (4th ed. 1998).

It is difficult, if not impossible, for average health consumers to collect, evaluate and analyze all the information necessary to compare competing forms of treatment for an illness with which they have been diagnosed. They are therefore unlikely to be able to act like the rational, well-informed consumers described in economics textbooks. Furthermore, while doctors may be sufficiently well informed about the efficacy of alternate courses of treatment, individual physicians are unlikely to be able to comparatively compute their marginal costs and benefits—particularly as the costs are not borne directly by the physician, but rather by either patients or taxpayers; for such a level of reasoned decisionmaking, guidance from a body such as the PBAC is essential. Indeed, the PBS uses a team of experts to make judgments about the relative merits of alternative pharmaceutical substances.[23] Such a system not only ensures that those with the relevant expertise conduct the comparisons, but also ensures that the costs of conducting the analysis are pooled across all health consumers.

Ironically, despite the contention that the PBS reduces the incentives for innovation, the scheme's heavy reliance on comparative cost-benefit analyses actually promises that only innovative products that deliver demonstrable benefits will receive the benefits of subsidies—thereby aiming to discourage the development of "copy cat" (or "me-too") drugs. Drug pricing systems that do not make extensive use of such economic analyses provide an incentive for pharmaceutical companies to invest heavily in advertising (to take advantage of the information asymmetry between manufacturers and consumers) rather than product innovation (which would be rewarded by a cost-benefit analysis if new benefits could be demonstrated).[24] In a typical market where individual buyers are poorly informed, the development of "copy cat" drugs, backed up by substantial advertising expenditures to achieve superficial product differentiation, is likely to be a more profitable strategy than the development of new substances.

Finally, it is necessary to address the contention that policies such as

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23. Once again, it is important to note that if an individual disagrees with a decision not to list a drug for subsidy on the PBS, he or she is free to purchase that drug, at the price chosen by the pharmaceutical company, as long as it has been deemed safe by the TGA. *See infra* text accompanying note 12.

24. Despite the attempts of some in the United States to introduce reforms to the pharmaceutical industry designed to lower consumer prices, the U.S. federal government has actually legislated to prohibit the use of economic evaluations through the Medicare Modernization Improvement Act of 2003. *See, e.g.*, Rosa L. DeLauro, *DeLauro Spearheads Letter to Trade Rep. Zoellick Regarding Rx Drug Reimportation* (Dec. 15, 2003), http://www.house.gov/delauro/press/2003/Zoellick_letter_12_16_03.html.

the Australian PBS drive up pharmaceutical prices in other, less regulated, markets. While high rates of profit in the pharmaceutical industry are typically defended as being necessary in order to fund more research and development,[25] it is neither obvious, nor inevitable, that higher pharmaceutical prices in Australia will result in increased research and development or lower pharmaceutical prices in the United States. The only reason that a for-profit company would pass on the benefits of higher prices or lower costs achieved in one market to consumers in another market was if they were under competitive pressure to do so. While it is possible that drug companies could chose to redistribute the gains they make from Australian consumers to U.S. consumers, it is also possible, and more likely, that they would pass any gains made in Australia directly to their U.S. shareholders instead.[26] It is worth noting that, in Australia, U.S. drug companies are continuing to maintain that the United States-Australia FTA will not lead to an increase in the prices paid by Australian consumers.[27] Putting aside the merits of this assertion, it seems inconsistent for the drug companies to simultaneously maintain that there will be no increase in drug prices (and thus, that it is in Australia's interests to sign the FTA), while suggesting that the FTA will result in a fairer worldwide distribution of the costs of pharmaceutical research and development.

THE PBS AND THE UNITED STATES-AUSTRALIA FTA

Despite the fact that the PBS does not, in any way, act as a barrier to trade between Australia and the United States, the office of the U.S. Trade

25. For example, the industry is fond of citing Joseph DiMasi's estimates of the high cost of drug research and development. Joseph A. DiMasi et al., *The Price of Innovation: New Estimates of Drug Development Costs*, 22 J. HEALTH ECON. 151 (2003). For responses to DiMasi's methods and calculations, see ROBERT YOUNG & MICHAEL SURRUSCO, RX R&D MYTHS: THE CASE AGAINST THE DRUG INDUSTRY'S "SCARE CARD" (2001) (responding to DiMasi's original study) and Richard G. Frank, Editorial, *New Estimates of Drug Development Costs*, 22 J. HEALTH ECON. 325 (2003).

26. If anything, it is competition that ensures that prices fall, not higher profits extracted in other markets. However, competition within the U.S. drug industry has not prevented it from remaining the most profitable industry in the United States over the past ten years. *See* FAMILIES USA, PROFITING FROM PAIN: WHERE PRESCRIPTION DRUG DOLLARS GO (July 2002), http://www.familiesusa.org/site/DocServer/PPreport.pdf?docID=249. It is unlikely that any gains to pharmaceutical companies from Australian consumers would be redirected to the pockets of U.S. consumers.

27. *See* MEDICINES AUSTL., MEDICINES AUSTRALIA WELCOMES FTA ANNOUNCEMENT (Feb. 9, 2004).

Representative stated in its *2003 National Trade Estimate Report on Foreign Trade Barriers*: "Research-based U.S. pharmaceutical firms are disadvantaged by several Australian Government policies. These include a reference pricing system that ties the price of an innovative U.S. medicine to the lowest price medicine in the same therapeutic or chemical group, regardless of patent status of the medicines."[28]

There is no doubt that drug companies are adversely affected by the fact that the Australian government refers to the prices of existing alternatives when deciding how much it is willing to pay for a new drug; that is, after all, the objective of the PBS. But this disadvantage, in the form of lower profits, is not derived from any barrier to trade. It is derived from the implementation, in Australia, of a pharmaceutical pricing scheme designed explicitly to counter the bargaining power of all pharmaceutical companies over their customers.

United States-based pharmaceutical interests also sought to change Australia's intellectual property (IP) laws through the United States-Australia FTA in order to extend the period of time during which drugs were protected from low-cost generic pharmaceuticals.[29] While there was no attempt to extend the actual twenty year patent life of pharmaceuticals, there was an attempt to change IP laws to impede manufacturers of generic pharmaceuticals from getting their products on to the market as soon as the twenty year patent life ended.[30] The practice by generic manufacturers of using the data collected by the patent holder to convince regulators of the safety and efficacy of a substance is known as "springboarding," and is officially recognized by the World Trade Organization (WTO).[31] As the following quotation from the U.S. Trade Representative shows, pharmaceutical companies have convinced U.S. trade negotiators that the ability to use old test data is a barrier to trade: "The Australian Government is considering allowing 'springboarding,' allowing generic pharmaceutical manufacturers to begin trials and production of pharmaceuticals so that these drugs can receive immediate patent approval and can be sold immediately after a patent expires."[32] By

28. U.S. TRADE REPRESENTATIVE, 2003 NATIONAL TRADE ESTIMATE REPORT ON FOREIGN TRADE BARRIERS 12 (2003), http://www.ustr.gov/reports/nte/2003/australia.pdf.

29. *See id.*

30. *See id.*

31. The WTO upheld Canada's right to allow a "Regulatory Review Exception" to patent law. World Trade Org., Panel on Canada, *Canada – Patent Protection of Pharmaceutical Products*, WT/DS114/R, at 146-48 (Mar. 17, 2000), *available at* http://www.wto.org/english/tratop_e/dispu_e/7428d.pdf.

32. U.S. TRADE REPRESENTATIVE, *supra* note 28, at 11.

delaying the launch of generic competition, patent holders can extend the period over which they receive the high prices that patents deliver. It has been estimated that for every extra year that generic drugs can be kept out of the Australian market the profits made by drug companies will increase by one billion Australian dollars.[33]

At the time of writing, the text of the FTA negotiated between Australia and the United States has not been made available for public scrutiny. It is, however, illustrative of the lack of transparency in the process that summaries of the deal released by the Australian and U.S. administrations differ substantially on the issue of negotiated changes to the PBS. The U.S. Trade Representative's website states: "Australia will make a number of improvements in its Pharmaceuticals Benefits Scheme (PBS) procedures that will enhance transparency and accountability in the operation of the PBS, including establishment of an independent process to review determinations of product listings."[34] Yet, the Australian Department of Foreign Affairs and Trade simply states: "The Pharmaceutical Benefits Scheme (PBS), in particular the price and listing arrangements that ensure Australians access to quality, affordable medicines, remains intact."[35]

INTERNATIONAL IMPLICATIONS

Australia's PBS is a highly effective and efficient public policy device that provides Australian citizens with some of the lowest pharmaceutical prices in the developed world. However, the effectiveness of the PBS has drawn criticisms from the U.S. pharmaceutical industry and, in turn, from the office of the U.S. Trade Representative that threaten its future.

As highlighted earlier, if Australian citizens paid as much for their pharmaceuticals as their counterparts in the United States the cost of purchasing pharmaceuticals would increase by between AUD$1 and AUD$2.4 billion per year;[36] further, if the pharmaceutical companies succeed in achieving changes to IP laws to delay the introduction of generics after the expiry of patents, the cost is likely to exceed AUD$1

33. LOKUGE & DENNISS, *supra* note 4 at 2.

34. U.S. TRADE REPRESENTATIVE, FREE TRADE "DOWN UNDER": SUMMARY OF THE U.S.-AUSTRALIA FREE TRADE AGREEMENT (Feb. 8, 2004), *available at* http://www.ustr.gov/releases/2004/02/2004-02-08-factsheet-australia.pdf.

35. AUSTRADE, FREE TRADE AGREEMENT WITH THE UNITED STATES (Feb. 9, 2004), *available at* http://www.austrade.gov.au/corporate/layout/0,0_S1-1_CORPXID0054-2_-3_PWB110416012-4_-5_-6_-7_,00.html.

36. LOKUGE & DENNISS, *supra* note 4, at ix.

billion per year.[37]

While such sums of money are no doubt substantial, they are far more likely to affect public health in Australia than to impact the pharmaceutical industry. These numbers are simply not so large when viewed in terms of the industry's global profits; for example, in 2001 the ten largest U.S. drug companies had a combined revenue of $U.S.167 billion.[38] However, an increase of this magnitude would represent a highly significant change in the Australian government's expenditure on pharmaceuticals, as at present the cost to the government of pharmaceutical subsidies is on the order of five billion Australian dollars. It has been estimated that the price charged to patients would need to nearly double, or the government would have to exact tax increases.[39] As discussed below, such an increase in the cost of pharmaceuticals to patients is likely to have a serious impact on public health.

The biggest threat to the pharmaceutical industry posed by the PBS is arguably not its minimal impact on global pharmaceutical profits, but it's appeal as an approach and the corresponding threat that other countries may begin to implement similar schemes. While the United States-Australia FTA does not provide a direct mechanism for drug companies to affect the pharmaceutical schemes of other counties, the negotiation process highlights the likely pressures that other countries will face should they seek to limit prices in any way. All countries, including the United States itself,[40] are struggling to reconcile consumers' demand for new medicines (many of which are very expensive) and the need to have equitable access to them, with the desire to keep taxes and public expenditure low. One of

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37. 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.

38. FAMILIES USA, *supra* note 26.

39. LOKUGE & DENNISS, *supra* note 4, at x.

40. Commenting on the problems faced by state governments in the United States, 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 is eroding individual's health care and is a large factor in the massive state deficit." Eric Durr, *GlaxoSmithKline Charged with Inflating Prices*, TRIANGLE BUS. J., Feb. 13, 2003, *available at* http://triangle.bizjournals.com/triangle/stories/2003/02/10/daily37.html. Even President Bush's brother, Florida Governor Jeb Bush, has stated that "[p]rotecting the large profit margins for the 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." Jeff Tieman, *A Formulary in Progress, Florida Panel Will Make Regular Changes to Medicaid List of Preferred Drugs*, MOD. HEALTHCARE, Sept. 10, 2001.

the easiest ways to reconcile these competing objectives is to follow Australia's lead and to restrict the price associated with new medicines.

In recent years the United States has shifted much of its international trade focus away from multilateral agreements and towards bilateral agreements.[41] The FTA between Australia and the United States was one of the first bilateral agreements between the United States and a developed country. The willingness of the United States negotiating team to pursue the operation of social policies within Australia, rather than to confine itself to issues of tariffs and quotas, is therefore likely to signal the nature of subsequent FTAs negotiated by the United States. The United States-Australia FTA negotiations were explicitly used as a mechanism for watering down Australia's PBS system.

While the notion that low cost production techniques will spread rapidly between countries engaged in trade with each other is widely accepted, the view that all countries should converge upon uniform modes of social service provision is, perhaps, less widely held. It is therefore important to consider the implications of the inclusion of social policies in FTAs between developed countries as, over time, differences that have developed to meet the differing democratic preferences of counties may be difficult to maintain.

The Australian PBS, with its combination of government subsidy, cost-benefit based price control, and low up-front prices for consumers (particularly concession card holders) ensure that drug prices do not create a significant barrier for Australians seeking medical treatment. According to one source, while sixteen percent of elderly residents of the United States spent more than one hundred U.S. dollars per month on prescription drugs, no elderly Australians spent that much despite the proportion of the populations that required them to take prescription medicines being quite similar.[42]

Access to affordable pharmaceuticals provides an important plank on which equity is delivered in Australia and is an essential component of the country's health system. Movement towards a system in which the chronically ill and the elderly are asked to pay higher prices will reduce

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41. *See, e.g.*, JOHN AUDLEY, CARNEGIE ENDOWMENT FOR INT'L PEACE, BAD BILATERAL TRADE DEALS ARE NO BETTER THAN BAD MULTILATERAL DEALS (Oct. 2003), http://www.ceip.org/files/pdf/issuebrieftoct2003.pdf.

42. CATHY SCHOEN ET AL., THE ELDERLY'S EXPERIENCES WITH HEALTH CARE IN FIVE NATIONS: FINDINGS FROM THE COMMONWEALTH FUND 1999 INTERNATIONAL HEALTH POLICY SURVEY 13 (May 2000), *available at* http://www.cmwf.org/programs/international/schoen_5nat_387.pdf.

public health outcomes, as well as equity, and will increase expenditures in other areas of the health budget, such as hospitals, where the adverse consequences of patients failing to take appropriate medicines will become apparent.

CONCLUSION

The PBS is not a barrier to trade; it is a barrier to excessive profits from the sale of pharmaceuticals in Australia. The PBS relies on the intervention of the government, on behalf of health consumers, to counter the monopoly power that patents provide to pharmaceutical manufacturers and to assist with reducing the information asymmetry between individual health consumers or providers and pharmaceutical manufacturers.

The U.S. trade negotiators showed themselves to be more than willing to act on behalf of the pharmaceutical industry in negotiating an FTA with Australia. When the final text of the FTA is released, it will be possible to evaluate more comprehensively the wins that have been achieved and losses that have been suffered. It seems that Australia has granted some concessions, including the establishment of a new appeals body. It does not seem incautious to predict that the changes negotiated as part of the FTA between Australia and the United States will likely result in higher prices for Australian consumers and higher profits for drug companies.

On a broader level, perhaps the most dangerous precedent that has been established in the United States-Australia FTA is that it now appears that even developed countries such as Australia may be susceptible to sacrificing their social policies in pursuit of improved access to the U.S. marketplace. In bilateral trade agreements, the far superior bargaining power of the United States may be too much for foreign governments to resist, especially when the full costs of their concessions will not be felt for some time.