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Bartering with a Nation's Health or Improving Access to Pharmaceuticals? The United States-Australia Free Trade Agreement

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BARTERING WITH A NATION'S HEALTH OR IMPROVING ACCESS TO PHARMACEUTICALS? THE UNITED STATES-AUSTRALIA FREE TRADE AGREEMENT

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Abstract: Providing access to affordable medicines and rewarding innovation produces a difficult tension in the global economy. Different nations deal with this tension differently, as illustrated by the United States-Australia Free Trade Agreement ("U.S.-Australia FTA") negotiations. Both nations stood to benefit greatly from reduced or eliminated tariffs. During negotiations, both nations sought to capitalize on the opportunity to alter certain practices that hindered trade. One such practice was Australia's fifty-five-year-old Pharmaceutical Benefits Scheme ("PBS"). The PBS controls prices for most medicines within Australia. Australian consumers are concerned that the U.S.-Australia FTA will adversely affect access to affordable medicines because free trade agreements are generally intended to remove tariffs as well as non-tariff barriers to trade between the parties. This agreement, however, leaves Australia's subsidization program intact. Similar concerns have been raised before, specifically in Canada over the North American Free Trade Agreement ("NAFTA"). Canada, however, is still able to provide access to affordable, yet innovative drugs, even after NAFTA. Australia will be able to do the same well after the U.S.-Australia FTA is fully implemented. The provisions of the U.S.-Australia FTA are minor procedural changes and do not substantively change how the PBS operates.

I. INTRODUCTION

A tension exists in the global economy between rewarding innovation with economic incentives and providing universal access to effective medicines. On the one hand, economic incentives encourage the creation of new, life-saving drugs. On the other hand, making life-saving drugs available and affordable to everyone who needs them is beneficial to society as a whole. Different nations have addressed this tension in a multitude of ways, from strong intellectual property protection to government-imposed price controls, and from bulk purchasing agreements to open market

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competition.[1] Australia and the United States have historically approached the tension differently with regard to pharmaceuticals.

Australia has dealt with the tension between rewarding innovation and providing access to medicines through a universal subsidization scheme. The program operates to ensure all Australians have timely access to essential medicines.[2] The PBS is grounded in social justice values and designed to maximize health outcomes.[3] The program uses its purchasing power to lower drug costs, and subsidizes the cost of most medicines, so that the Australian consumer is not paying a true market price.[4] Typically, subsidization is a protectionist measure in which a government pays a domestic producer so that the producer's products are protected from competition in the open market.[5] In this case, however, the purpose of the subsidization is to protect the consumer from the open market by subsidizing drug prices.[6]

By contrast, the United States has a longstanding history of using a competitive market approach to contain drug costs.[7] This approach focuses on the importance of economic incentives to encourage the development of new drugs. Competitive markets[8] allow pharmaceutical companies to

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[1] *See* INT'L. TRADE ADMIN., U.S. DEP'T. OF COM., PHARMACEUTICAL PRICE CONTROLS IN OECD COUNTRIES, IMPLICATIONS FOR U.S. CONSUMERS, PRICING, RESEARCH AND DEVELOPMENT, AND INNOVATION (2004), *available at* http://www.ita.doc.gov/drugpricingstudy (last visited May 31, 2005) [hereinafter Price Control Report] (providing a report on eleven countries' methods of addressing this tension). This report was prepared as required by section 1123 of the Medicare Prescription Drug Modernization and Improvement Act of 2003, Pub. L. No. 108-173, § 117 Stat. 2066.

[2] *See* MAURICE RICKARD, PARLIAMENT OF AUSTRALIA, THE PHARMACEUTICAL BENEFITS SCHEME: OPTIONS FOR COST CONTROL (May 28, 2002), *available at* http://www.aph.gov.au/library/pubs/CIB/2001-02/02cib12.htm (last visited May 31, 2005).

[3] *See id.* (asserting that access to medicines, both physical and financial, increases the level of health in society).

[4] *See* Clive Hamilton, Buddhima Lokuge, & Richard Denniss, *Barrier to Trade or Barrier to Profit? Why Australia's Pharmaceutical Benefits Scheme Worries U.S. Drug Companies*, 4 YALE J. HEALTH POL'Y L. & ETHICS 373, 375, 378 (2004).

[5] JOAN EDELMAN SPERO & JEFFREY A. HART, THE POLITICS OF INTERNATIONAL ECONOMIC RELATIONS 386 (Beth Gillett ed., St. Martin's Press 1997) (1977).

[6] *See* AUSTRALIAN GOVERNMENT DEPARTMENT OF HEALTH AND AGEING, ABOUT THE PBS, *available at* www.health.gov.au/internet/wcms/publishing.nsf/content/health-pbs-general-aboutus.htm (last visited May 31, 2005) [hereinafter ABOUT THE PBS].

[7] *See* PHARMACEUTICAL RESEARCH MANUFACTURERS OF AMERICA (PHRMA), Q & A TOUGH QUESTIONS, STRAIGHT ANSWERS (2004), *at* http://www.phrma.org/publications/publications//2004-08-20.1049.pdf (last visited May 31, 2005) (asserting that "the United States contains costs through the use of a competitive market" and that government controls may reduce or delay access to specific drugs).

[8] There are no universal subsidization programs offered by the U.S federal government for pharmaceuticals. In fact, the Medicare Prescription Drug Modernization and Improvement Act of 2003, Pub. L. No. 108-173, §1860D-11(i), explicitly reaffirms the role of competition and forbids the Secretary of Health and Human Services from interfering with negotiations between drug manufacturers and pharmacies or instituting a price structure for the reimbursement of Medicare Part D drugs. *See* TERRI SHAW, CENTER FOR AMERICAN PROGRESS, PRESCRIPTION DRUG PRICES: HARNESSING MEDICARE'S PURCHASING POWER,

maximize profits in order to reinvest them in research and development.[9] The U.S. government has made it known that it wants competitive markets to prevail worldwide and endeavors to accomplish this goal through several means, including free trade agreements.[10]

Given these differences, it was no surprise that the onset of negotiations for a free trade agreement between Australia and the United States triggered concern among stakeholders in both countries regarding the agreement's potential impact on pharmaceuticals. The removal of non-tariff barriers such as government purchasing practices is just as important to a successful free trade agreement as the removal of tariffs.[11] The United States perceived the PBS subsidy as a non-tariff barrier to trade,[12] but Australia did not.

Although both governments publicize the benefits of the U.S.-Australia FTA to their respective economies and citizens,[13] Australian consumers remain concerned[14] that the U.S.-Australia FTA will negatively impact the PBS and their ability to obtain affordable medicines. However, the free trade agreement neither eliminated the PBS, nor made any substantive changes to it.

Jan. 28, 2004, *available at* http://www.americanprogress.org/site/pp.asp?c=biJRJ8OVF&b=24890 (last visited May 31, 2005).

[9] *See* Price Control Report, *supra* note 1 at vii. *See also* Gregory J. Glover, *Competition in the Pharmaceutical Marketplace*, Part II, PhRMA (Mar. 19, 2002) *available at* http://www.phrma.org/actions/printFriendlyPage.cfm?t=46&r=432 (last visited May 31, 2005) (asserting that companies need exclusivity period in order to raise the money to pay for research and development).

[10] *See generally* Price Control Report, *supra* note 1.

[11] DAVID N. BALAAM & MICHAEL VESETH, INTRODUCTION TO INTERNATIONAL POLITICAL ECONOMY 233 (Laura Pearson ed., Prentice Hall 2001).

[12] *See* Office of the United States Trade Representative ("USTR"), U.S.-AUSTRALIA FREE TRADE AGREEMENT—QUESTIONS AND ANSWERS ABOUT PHARMACEUTICALS (July 8, 2004), *available at* http://www.ustr.gov/Document_Library/Fact_Sheets/2004/U.S.-Australia_Free_Trade_Agreement_--_Questions_Answers_About_Pharmaceuticals.html (last visited May 31, 2005); Elizabeth Becker & Robert Pear, *Trade Agreement May Undercut Importing of Inexpensive Drugs*, N.Y. TIMES, Jul. 24, 2004.

[13] *See* Media Release, The Honorable Mark Vaile, MP, Minister for Trade, Australia, Historic Free Trade Agreement Begins Today (Jan. 1, 2005), *available at* http://www.trademinister.gov.au/releases/2005/mvt001_05.html (last visited May 31, 2005) (claiming that the free trade agreement is worth billions of dollars); Press Release, USTR, United States and Australia Sign Free Trade Agreement, *available at* http://www.ustr.gov/Document_Library/Press_Releases/2004/May/United_States_Australia_Sign_Free_Trade_Agreement.html (last visited May 31, 2005) (declaring this free trade agreement as "the most significant immediate reduction of industrial tariffs ever achieved in a U.S. free trade agreement.").

[14] *See e.g., Drug Companies Want FTA Changes*, AAP, Oct. 21, 2004 (noting concern about drug companies ceasing research and development in Australia); Ken Harvey, Thomas A. Faunce, Buddhima Lokuge, & Peter Drahos, *Will the Australia-United States Free Trade Agreement Undermine the Pharmaceutical Benefits Scheme?*, eMJA, July 25, 2004, *available at* http://www.mja.com.au/public/rop/ausfta/har10408_fm.html (last visited May 31, 2005) (discussing several trade agreement provisions that threaten the PBS); Jason Frenkel, *More New Medicines, But at a Price*, HERALD SUN, Feb. 10, 2004, at 5 (suggesting the price of pharmaceuticals will rise because of the trade agreement).

A similar situation existed between the United States and Canada prior to Canadian free trade agreements with the United States. Like Australia, Canada sought to protect its citizens from high drug prices and faced pressure from the American drug industry.[15] Although the free trade agreements changed how Canada maintained low drug prices, Canada is still able to control the price of patented pharmaceuticals.[16] The changes to the Canadian system under the free trade agreements were more extensive than those under the U.S.-Australia FTA, yet Canadian consumers still have access to affordable medicines.[17] Judging from the limited impact of the U.S.-Canada free trade agreements on drug prices in Canada, the minor changes to the PBS in the U.S.-Australia FTA should not impact Australia's ability to ensure access to affordable medicines.[18]

This Comment asserts that the U.S.-Australia FTA will not harm the Australian consumer's ability to obtain affordable drugs through the PBS. Part II discusses the background of the Australian PBS subsidization program. Part III explores the Canadian system of ensuring access to affordable medicines before the free trade agreements and demonstrates its similarities with the Australian approach. Part IV compares the free trade agreement's effect on the Canadian pharmaceutical market with the likely effect of the U.S.-Australia FTA on Australian pharmaceuticals. It also discusses the U.S.-Australia FTA modifications to the PBS and argues that these changes, along with Australia's influential public opinion, will ensure a minimal impact on the price of drugs in Australia.

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[15] *See e.g.*, Letter from Pharmaceutical Research Manufacturers of America (PhRMA) to USTR (last updated Sept. 18, 2000) *available at* http://www.cptech.org/ip/health/phrma/301-00/canada.html (last visited May 31, 2005) (urging the United State government to list Canada as a Priority Watch Country because of its failure to offer acceptable patent protection for pharmaceuticals) [hereinafter Letter from PhRMA to USTR].

[16] See discussion *infra* Part III.

[17] This is primarily accomplished through the Patented Medicine Prices Review Board ("PMPRB"). *See* PMPRB ANN. REP. 3 (2002), *available at* http://www.pmprb.com/CMFiles/ar2002e21LEF-6252003-6142.pdf (last visited May 31, 2005) ("The PMPRB protects consumers and contributes to Canadian health care by ensuring that prices charged by manufacturers for patented medicines are not excessive."). *See also infra* Part III.C. (discussing the PMPRB in more detail).

[18] *See* Phillip Davies, Deputy Secretary, Department of Health & Aging, Remarks at the AUSFTA Conference (Mar. 1-2, 2004), *at* http://www.apec.org.au/docs/fta04Davies.pdf (last visited May 31, 2005).

II. THE AUSTRALIAN SYSTEM OF PROVIDING ACCESS TO AFFORDABLE DRUGS WAS EFFECTIVE BEFORE THE U.S.-AUSTRALIA FTA WAS IMPLEMENTED

Before the U.S.-Australia FTA, Australia managed consumer access to affordable drugs through the Pharmaceutical Benefits Scheme ("PBS").[19] The PBS maintains this role post-U.S.-Australia FTA. Australia passed the National Health Act [of] 1953 that recognized access to essential medicines as a priority and created the PBS.[20] The PBS employs an extensive process for listing and pricing high-quality medicines.[21] This process ensures access to low-priced medicines, both patented and generic versions.[22] Before the U.S.-Australia FTA, the PBS was so effective the World Health Organization hailed the PBS as a benchmark by which other countries' health programs should be measured.[23] Similarly, the PBS was "regarded as the 'gold standard'" of medicine-access programs worldwide.[24]

A. The Goal of the PBS Is to Ensure Access to Affordable Drugs

The PBS seeks, primarily, to ensure that all Australians have reliable, timely, and affordable access to new, expensive, therapeutic drugs.[25] The PBS first offered benefits in 1948.[26] Initially, the PBS supplied a limited number of life-saving or disease-preventing drugs free of charge.[27] The program has grown significantly and now provides subsidized access to

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[19] AUSTRALIAN GOVERNMENT DEPARTMENT OF HEALTH & AGEING, FREQUENTLY ASKED QUESTIONS, *available at* http://www.health.gov.au/internet/wcms/publishing.nsf/Content/health-pbs general-faq.htm-copy2#about2_0 (last visited May 31, 2005).

[20] National Health Act, 1953, § 85 (Austl.). *See* ABOUT THE PBS *supra* note 6 (noting the operations of the PBS are embodied in Part VII of the National Health Act 1953).

[21] *See* Centre for International Economics, Economic Analysis of AUSFTA, §4, *available at* http://www.dfat.gov.au/trade/negotiations/us_fta/economic_analysis_report/ (last visited May 31, 2005) (describing the several steps drug taken by manufacturers to have a drug listed and priced with the PBS) [hereinafter Economic Analysis]; *see also infra* Part II.B (describing the process of listing and pricing a drug on the PBS).

[22] *See* AUSTRALIAN PARLIAMENT LIBRARY, DR. KATE BURTON & JACOB VARGHESE, THE PBS AND THE AUSTRALIA-US FREE TRADE AGREEMENT, No. 3, July 21, 2004, *available at* http://www.aph.gov.au/library/pubs/rn/2004-05/05rn03.pdf [hereinafter PBS & AUSFTA].

[23] Janaki Kremmer, *Australia's Low-Cost Drugs Threatened By US Trade Deal*, CHRISTIAN SCI. MONITOR, Aug. 16, 2004, LEXIS, Nexis Library, News Group File.

[24] *Drug Spat Stalls Australia-US Free Trade Deal*, AGENCE FRANCE PRESS, Aug. 4, 2004. *But see Taxes Foot Drug Scheme Mark-up*, HERALD SUN, Apr. 22, 2003, at 8.

[25] ABOUT THE PBS, *supra* note 6.

[26] AMANDA BIGGS, PARLIAMENTARY LIBRARY, THE PHARMACEUTICAL BENEFITS SCHEME—AN OVERVIEW (Jan. 2, 2003), *available at* http://www.aph.gov.au/library/intguide/SP/pbs.htm (last visited May 31, 2005) [hereinafter PBS OVERVIEW].

[27] *See id.* (containing a summary of the evolution of the PBS).

approximately 600 prescription medications,[28] which equates to about eighty percent of all prescribed drugs.[29] The subsidization by the Australian government is so substantial that for every dollar a patient spends, the PBS spends five.[30] The PBS also caps the cost of prescriptions for specific populations including chronically-sick people who require multiple prescriptions, and pensioners.[31] Non-pensioners' cost per prescription is lowered after their annual prescription costs exceed a certain amount.[32]

This system is expensive, costing the government more than AUS $5.6 billion per year.[33] In 2003, the PBS was the fastest growing area of health expenditure.[34] The cost of the PBS rose by an average expenditure growth rate of around fourteen percent each year between 1992 and 2002.[35] The increase is attributable to several factors, including increasingly expensive new drugs listed through the PBS, over-prescribing by physicians, consumer expectations, the aging population of Australia, and aggressive marketing by the pharmaceutical industry.[36] Nonetheless, the PBS saves Australia about AUS $1–$2.5 billion through its listing and pricing strategy.[37]

B. *The PBS Drug Listing and Pricing System Helps to Meet the Goal of Ensuring Access to Affordable Drugs*

The thorough process for listing a drug with the PBS keeps drug prices low.[38] Before a drug manufacturer can apply to have a drug listed, the Australian Drug Evaluation Committee ("ADEC") must approve it.[39] ADEC

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[28] Peter Sainsbury, *Australia-United States Free Trade Agreement and the Australian Pharmaceutical Benefits Scheme*, 4 YALE J. HEALTH POL'Y, L. & ETHICS 387, 388 (2004). It is difficult to determine the number of drugs listed because drugs come in many forms and strengths, and are listed under various brand names. *Id.*

[29] ABOUT THE PBS, *supra* note 6. On average, this is eight prescriptions per person in Australia. *Id.*

[30] PBS OVERVIEW, *supra* note 26. Pensioners include "part pensioners, Veterans Affairs beneficiaries, sickness allowees and other older long-term allowees, including parenting allowees over 60 and receiving income support for at least 9 months." *Id.*

[31] *Id.*

[32] *Id.*

[33] ABOUT THE PBS, *supra* note 6.

[34] PBS OVERVIEW, *supra* note 26.

[35] *See* RICKARD, *supra* note 2.

[36] *See id.* (listing 8 reasons for the increase in cost).

[37] Sainsbury, *supra* note 28, at 389 (compared to the United States).

[38] The following describes the process in existence prior to the FTA, which for the most part still exists post-FTA. For procedural changes resulting from the conclusion of US-Australian FTA, *see infra* Part IV.

[39] PBS OVERVIEW, *supra* note 26. The Therapeutic Goods Administration is analogous to the U.S. Food & Drug Administration. *See* Hamilton, Lokuge, & Denniss *supra* note 4 (calling the Therapeutic Goods Administration and the Food & Drug Administration rough equivalents).

is a part of the Therapeutic Goods Administration.[40] This committee evaluates a drug for its safety, quality, and efficacy.[41] Once approved by ADEC, a manufacturer may market and sell the drug to the public without being listed on the PBS. However, at this stage, the PBS will not subsidize its cost.[42]

After ADEC approval, there are two primary reasons a drug sponsor[43] would be interested in listing its product with the PBS. First, if a drug is on the list, the PBS will subsidize its price, making the price closer or equal to alternative drugs also listed with the PBS.[44] Drugs that are not subsidized do not sell well in Australia because they are more expensive than their subsidized alternatives.[45] Second, the PBS orders listed drugs in large quantities, which results in transactional cost savings to the manufacturer as well as stability and reliability.[46]

For a drug to become listed on the PBS, the sponsor must first apply to the Pharmaceutical Benefits Advisory Committee ("PBAC") for assessment.[47] The PBAC evaluates the drug for its therapeutic value, and compares its cost effectiveness with existing treatments.[48] The drug's manufacturer submits information to assist in this evaluation, including clinical trial data and the manufacturer's requested price.[49] The PBAC then determines whether the drug will be listed with the PBS.[50]

After a drug has cleared the PBAC process and is approved for listing, the Minister for Health and Ageing refers it to the Pharmaceutical Benefits

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[40] PBS OVERVIEW, *supra* note 26.

[41] *See* RICKARD, *supra* note 2.

[42] For a discussion on the pricing process of the PBS, see *infra* Part II.C.

[43] A sponsor is usually the drug company, but could also be a medical body, health professionals, or private individuals and their representatives. *See* PBS OVERVIEW, *supra* note 26.

[44] *See* ABOUT THE PBS, *supra* note 6.

[45] Clara Pirani, *Leaders Face Challenge on Trade Threat to PBS*, THE AUSTRALIAN, Sept. 27, 2004, LEXIS, Nexis Library, News Group File (stating that "[m]edicines not subsidized by the scheme sell poorly in Australia, so it is better for a drug company to have its product on the list even though their profit margin is reduced.").

[46] *See* Sainsbury, *supra* note 28, at 390; DR. MAURICE RICKARD, PARLIAMENT OF AUSTRALIA, FREE TRADE NEGOTIATIONS, THE PBS, AND PHARMACEUTICAL PRICES (Feb. 10, 2004), *available at* http://www.aph.gov.au/library/pubs/rn/2003-04/04rn32.htm (last visited May 31, 2005).

[47] *See* DEPARTMENT OF HEALTH AND AGEING, OUTCOMES OF PHARMACEUTICAL BENEFITS ADVISORY COMMITTEE ("PBAC") MEETINGS, *available at* http://www.health.gov.au/internet/wcms/publishing.nsf/Content/health-pbs-general-outcomes.htm (last visited May 31, 2005).

[48] National Health Act, 1953 §101 (3A) (Austl.).

[49] *See* DEPARTMENT OF HEALTH AND AGEING, GUIDELINES FOR THE PHARMACEUTICAL INDUSTRY ON PREPARATION OF SUBMISSIONS TO THE PBAC: PART II, *available at* http://www.health.gov.au/internet/wcms/publishing.nsf/Content/health-pbs-general-pubs-pharmpac-part2.htm (last visited May 31, 2005).

[50] *See* PBS & AUSFTA, *supra* note 22. There is no formal threshold, but generally if the additional cost per life-year gained for a drug is less than AUS $42,000 (1998/99 values) it is approved, while drugs with a cost per life-year gained that exceed AUS $76,000 are not approved. *See* Sainsbury, *supra* note 28 at 389.

Pricing Authority ("Pricing Authority"),[51] the agency responsible for pricing all drugs listed with the PBS.[52] The Pricing Authority then recommends to Australia's Department of Health the price it should offer to pay the sponsor (usually the manufacturer) for the drug.[53] The price is determined after the Pricing Authority considers a list of factors, including the clinical and cost effectiveness, the prices of alternate brands already on the market, the level of activity undertaken by the company in Australia (including new investment, research and development), and overseas prices.[54] If a new drug does not have added benefits over an already listed drug, it is offered for the same price as the listed drug.[55] The Pricing Authority also recommends volume arrangements in order to lower the price.[56] This allows the PBS to use the bargaining power it gains from ordering in large quantities to reduce the price to be paid to the manufacturer.[57] If the manufacturer agrees with the recommended price, the drug is then added to the PBS list.[58] If, however, the drug's sponsor does not agree with the offered price, it can appeal to the Pricing Authority or the PBAC for reconsideration, or offer (or continue to offer) the drug on the open market.[59]

In addition to setting the price paid to the manufacturer, the PBS also sets the subsidized purchase price for the consumer.[60] Thus, the drug the consumer buys has been subjected to two levels of price reduction: quantity discount and government subsidization.[61] If a drug manufacturer does not list a drug with the PBS, the manufacturer can sell the drug on the open market, but it will compete with subsidized drugs. This is unlikely to be

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[51] *See* Economic Analysis, *supra* note 21.

[52] *See* PBS & AUSFTA, *supra* note 22.

[53] PHARMACEUTICAL BENEFITS PRICING AUTHORITY ANN. REP. 4 (2003), *available at* http://www.health.gov.au/internet/wcms/publishing.nsf/Content/health-pbs-general-pricing-pbparpt03.htm (last visited May 31, 2005) [hereinafter PBPA ANN. REP.].

[54] *Id.* The Pricing Authority also reviews prices to recommend adjustments. *Id.*

[55] *See* Kremmer, *supra* note 23.

[56] *See* KEN HARVEY, THE PHARMACEUTICAL BENEFITS SCHEME UNDER THREAT, *available at* http://home.vicnet.net.au/~hissues/Text/Harvey4.doc (last visited May 31, 2005) (reporting that the PBS purchases about ninety percent of prescription drugs).

[57] *See id.* at 2.

[58] *See* PBS & AUSFTA, *supra* note 22.

[59] *See id.*

[60] *See* ABOUT THE PBS, *supra* note 6.

[61] *See* Dr. K. Lokuge & Richard Denniss, *Trading in Our Health System? The Impact of the Australia-US Free Trade Agreement on the Pharmaceutical Benefits Scheme*, at x (The Australian Institute Discussion Paper Number 55, 2003), *available at* http://www.tai.org.au/Publications_Files/DP_Files/DP55suma.pdf (last visited May 31, 2005). "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." *Id.*

lucrative for the drug manufacturer, especially if there is an alternative drug on the market that is subsidized through the PBS.

C. *Generic Versions of Drugs Are Easier to List with the PBS Than Patented Versions, Resulting in Further Price Reductions for the Consumer*

It is easier to list a generic drug with the PBS than to list its patented counterpart.[62] The PBS simplified the application for approval of generic drugs through a process called "springboarding."[63] Springboarding allows a generic drug manufacturer to use the test data of the patent holder in its application for marketing approval by the Therapeutic Goods Administration.[64] Springboarding makes the approval process cheaper and easier for a generic drug applicant, because the applicant does not have to invest the time or resources in developing its own test data.[65] Instead, generic drug applicants can take advantage of the work of the patented manufacturer.[66]

Once approved by the Therapeutic Goods Administration, the generic drug producer may choose to apply to PBAC and the Pricing Authority for listing and pricing and be ready to enter the market the moment the patent expires.[67] As mentioned previously, the PBAC evaluates the drug for its therapeutic value and compares its cost effectiveness with existing treatments.[68] A generic version of an existing PBS drug has essentially the same therapeutic value and is more cost efficient for the PBS program; thus, it becomes a likely candidate for approval.[69] Not only is a generic drug more likely to be approved, but it costs less than a brand-name drug because of the lack of research and development costs.[70] Furthermore, once the PBAC recommends a generic drug to the Pricing Authority, the price offered to the generic producer will be less than that offered to the patent holder.[71]

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[62] *See* PBS & AUSFTA, *supra* note 22. For an explanation of how the FTA impacts the generic market, see *infra* Part IV.C.

[63] *See id.*

[64] *See* NICHOLAS TYACKE, THE IMPACT OF THE US FREE TRADE AGREEMENT ON THE GENERIC PHARMACEUTICAL INDUSTRY AND THE PBS, THE SKY IS NOT FALLING 6-7 (2004), *available at* http://www.claytonutz.com/downloads/FTA_Article_Aug04.pdf (last visited May 31, 2005).

[65] PBS & AUSFTA, *supra* note 22.

[66] *Id.*

[67] *Id.*

[68] *See* Economic Analysis, *supra* note 21.

[69] *See* Sainsbury, *supra* note 28 at 389.

[70] *See* Maria Moscaritolo & Paul Starick, *Drug Patents, Finding the Right Dose*, THE ADVERTISER, Aug. 5, 2004 at 21.

[71] *See* PBS & AUSFTA, *supra* note 22.

A generic medicine's entry into the market is facilitated by its cost savings for both the government and the consumer.[72] Generic drugs cost less, and therefore save both the PBS and consumers money.[73] The influx of generic drugs, which are cheaper to produce than their patented counterparts, forces a decrease in the price of the patented alternatives.[74] By making it easier for generic drugs to be on the PBS list, the PBS system helps ensure that low-priced drugs are available to the Australian consumer. In addition to subsidization measures, the goal of providing low-cost pharmaceuticals to the consumer is met by allowing generic drugs to enter the market.

III. FREE TRADE AGREEMENTS SUBSTANTIVELY CHANGED HOW CANADA ACHIEVES ACCESS TO AFFORDABLE MEDICINES, BUT CANADA CAN STILL CONTROL PHARMACEUTICAL PRICES

Before entering into free trade agreements with the United States,[75] Canada ensured access to affordable, innovative medicines primarily by promoting generic versions of drugs. Like Australia, Canada sought to meet its goal of providing its citizens with access to affordable medicines in part by favoring generic drugs in its pharmaceutical licensing policies.[76] The difference was in how the two nations actually promoted generics. While Australia used and still uses springboarding,[77] Canada promoted generics on the market through its patent laws.[78] Canada expedited the entry of generics into its market by allowing for compulsory licenses of the patented drug to a generic manufacturer and by issuing shorter patent rights protection.[79] Now,

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[72] *See* Moscaritolo & Starick, *supra* note 70 at 21.

[73] *See* PHARMACEUTICAL SOCIETY OF AUSTRALIA, PHARMACY SELF CARE, GENERIC MEDICINES (BRAND CHOICE - PRICE OPTIONS), June 2003, *available at* http://www.nationalpharmacies.com.au/advice_cards/fact%20card%20PDFs/GENERICS_FACT_CARD_03.pdf (last visited May 31, 2005).

[74] PBS & AUSFTA, *supra* note 22.

[75] Two free trade agreements between the United States and Canada influenced the way Canada regulated pharmaceuticals: the U.S.-Canada Free Trade Agreement in 1987 and NAFTA in 1993. *See infra* Parts III. B-C.

[76] *See* Mary Atkinson, *Patent Protection for Pharmaceuticals: A Comparative Study of the Law in the United States and Canada*, 11 PAC. RIM L. & POL'Y. 181, 190 (2002); Canadian HIV/AIDS Legal Network, *Evolution of Canadian Law on Pharmaceutical Pricing*, *available at* http://www.aidslaw.ca/Maincontent/issues/cts/DrugPricingE/evolution.htm (last visited May 31, 2005) [hereinafter *Evolution of Canadian Law*].

[77] *See supra* Part II.C (describing springboarding).

[78] *See* Patricia I. Carter, *Federal Regulation of Pharmaceuticals in the United States and Canada*, 21 LOY. L.A. INT'L COMP. L.J. 215, 241 (1999).

[79] *See* Atkinson, *supra* note 76, at 191.

Canada primarily uses a central control mechanism similar to Australia's PBS, called the Patented Medicines Prices Review Board ("PMPRB").[80]

A. *Compulsory Licenses Ensured Access to Innovative and Affordable Medicines in Canada*

Before Canada negotiated any free trade agreements with the United States it used a compulsory license system to ensure that generics would be available on the market so consumers could have access to affordable, yet innovative, pharmaceuticals.[81] In 1923, Canada limited exclusive pharmaceutical patent rights by allowing drug manufacturers to obtain compulsory licenses.[82] A compulsory license forces the patent holder to allow the licensee to manufacture and market the patented drug before the patent expires.[83] Canadian generic drug manufacturers applied for a license from the Commissioner of Patents to manufacture and market a generic counterpart to a patented drug before the patent had expired.[84]

In 1969, Canada removed the domestic manufacturer requirement, opening the door for non-domestic manufacturers to obtain a license, produce a generic drug outside of Canada, and sell the drug on the Canadian market.[85] The generic producer simply had to notify the patent holder in order to obtain a license.[86] The patent holder's royalty fee was as only four percent of the licensee's selling price.[87] Compulsory licensing only applied to patented pharmaceuticals not exploited by a patent holder within three years of the patent issue date.[88] This licensing system effectively shortened a patent's length and reduced the patent holder's market power by

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[80] PATENTED MEDICINE PRICES REVIEW BOARD, FREQUENTLY ASKED QUESTIONS, *available at* http://www.pmprb-cepmb.gc.ca/english/view.asp?x=272 (last visited May 31, 2005) [hereinafter PMPRB FAQ's].

[81] *See* Lars Noah, *NAFTA's Impact on the Trade in Pharmaceuticals*, 33 HOUS. L. REV. 1293, 1300 (1997).

[82] *See* Christopher Scott Harrison, *Protection of Pharmaceuticals as Foreign Policy: The Canada-U.S. Trade Agreement and Bill C-22 Versus the North American Free Trade Agreement and Bill C-91*, 26 N.C. J. INT'L L. & COM. REG. 457, 506 (2001).

[83] *See* Carter, *supra* note 78, at 241.

[84] *See* Atkinson, *supra* note 76, at 191.

[85] *See id.*

[86] *See* Ryan H. Flax, *NAFTA & the Patent Systems of Its Members: Is There Potential for a Unification of the North American Patent Systems?*, 5 NAFTA: LAW AND BUSINESS REVIEW OF THE AMERICAS 461, 470 (1999).

[87] *See* James M. Silbermann, *The North American Free Trade Agreement's Effect on Pharmaceutical Patents: A Bitter Pill to Swallow or a Therapeutic Solution?*, 12 J. CONTEMP. HEALTH L. & POL'Y 607, 622 (1996).

[88] *See* Arlene Nolan Farolan, *Harmonization of the Patent Systems of NAFTA Nations*, 10-SUM CURRENTS: INT'L TRADE L.J. 54, 61 (2001); Flax, *supra* note 86, at 476.

diminishing one of the biggest benefits of a patent—market exclusivity.[89] These licenses drove down the price of patented drugs and saved Canadian consumers millions of dollars.[90] Until 1987, this program produced some of the lowest consumer drug prices among developed nations.[91]

B. *The U.S-Canada Free Trade Agreement of 1987 Weakened Canada's Compulsory License System*

As early as 1982, the United States targeted Canada's compulsory license system as a trade issue because of the pharmaceutical industry's complaints that it was threatening profitability.[92] Compulsory licenses were a contested issue in the U.S.-Canada Free Trade Agreement negotiations.[93] In 1987, in response to pressure from the United States during the trade agreement negotiations, Canada passed Bill C-22 that strengthened patent holder rights and weakened the compulsory license system.[94]

Bill C-22 introduced different time frames for issuing compulsory licenses depending on the situation.[95] The time frames ranged from seven to ten years.[96] A generic drug producer manufacturing and selling a pharmaceutical domestically could apply for a compulsory license seven years after the issue date, provided the patent holder invented the drug outside of Canada.[97] However, a generic drug producer had to wait until ten years after the issue date to apply for a compulsory license if the producer only wanted to import the medicine instead of manufacturing it within Canada.[98] This new structure encouraged domestic generic manufacturing.[99]

The changes in Bill C-22 went beyond amending the compulsory licensing system and extended modifications to the patent system. Notably, the legislation extended the length of the patent to twenty years from the

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[89] *See* Carter, *supra* note 78, at 241.

[90] *See id.* at 241; Harrison, *supra* note 82, at 457 ("[An] economist Harry Eastman found that compulsory licensing saved Canadian consumers $ 211 million each year.").

[91] Harrison, *supra* note 82, at 457.

[92] *See id.* at 508-09.

[93] *See* Carter, *supra* note 78, at 242.

[94] An Act to Amend the Patent Act and Provide for Certain Matters In Relation Thereto, C. Gaz. ch. 41 (1987) (Can.) [hereinafter 1987 Patent Amendment]. *See also Evolution of Canadian Law*, *supra* note 76. *But see* Harrison, *supra* note 82, at 519 (quoting Canada's Finance Minister who insisted that Bill C-22 "was not . . . related to the free trade agreement.").

[95] 1987 Patent Amendment, *supra* note 94, at ch. 41.11 (2)(a).

[96] *Id.*

[97] *Id. See Evolution of Canadian Law*, *supra* note 76, at *8.

[98] *See* 1987 Patent Amendment, *supra* note 94, at ch. 41.11 (2)(c). *See also Evolution of Canadian Law*, *supra* note 76, at *8.

[99] *See Evolution of Canadian Law*, *supra* note 76, at *8.

date of filing.[100] Bill C-22 also allowed issuance of patents for medicines themselves, rather than just patenting the process for creating the medicines.[101] This new provision favored patent holders in two ways. First, it closed a loophole that allowed generic drug manufacturers to produce a patented drug via a different process. Second, it permitted a patent holder to not only protect the process of creating the drug, but also to protect the drug itself.

Before this free trade agreement, the crux of Canada's system was the use of compulsory licenses, which encouraged generic drugs producers to enter the market.[102] To monitor a potential increase in drug prices due to the changes to the compulsory licensing system, Canada established the PMPRB with limited powers.[103] PMPRB was an independent body charged with overseeing drug prices.[104] If the PMPRB found that a patent holder charged excessive prices, it could remove the protection against compulsory licensing.[105]

C. *Pressure by the United States During NAFTA Negotiations Caused More Changes to the Canadian System*

During the U.S.-Canada NAFTA negotiations, Canada made more changes to its laws relating to drugs under pressure from the United States.[106] Compulsory licenses were still an issue and NAFTA further limited their use.[107] Instead of liberally granting licenses to generic drug applicants whenever they met the conditions of Bill C-22, NAFTA tightened the rein by requiring that license requests be considered individually.[108] Under NAFTA, a manufacturer could obtain a license only if several terms

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[100] 1987 Patent Amendment, *supra* note 94, at ch. 46. Previously the patent length had been only seventeen years. *See Evolution of Canadian Law*, *supra* note 76, at *7.

[101] 1987 Patent Amendment, *supra* note 94, at ch. 14. *See Evolution of Canadian Law*, *supra* note 76, at *7.

[102] *See Evolution of Canadian Law*, *supra* note 76, at *7.

[103] 1987 Patent Amendment, *supra* note 94, at ch. 41.18. *See Evolution of Canadian Law*, *supra* note 76, at *8.

[104] PATENTED MEDICINE PRICES REVIEW BOARD, ABOUT THE PMPRB, *available at* http://www.pmprb-cepmb.gc.ca/english/View.asp?x=175&mp=87 (last visited May 31, 2005) [hereinafter ABOUT THE PMPRB].

[105] CANADIAN HIV/AIDS LEGAL, PATENTED MEDICINE PRICES REVIEW BOARD, http://www.aidslaw.ca/Maincontent/issues/cts/e-info-dp-03.pdf (last visited May 31, 2005) [hereinafter PATENTED MEDICINES].

[106] *See, e.g.*, Letter from PhRMA to USTR, *supra* note 15. *See also Evolution of Canadian Law*, *supra* note 76.

[107] *See* NAFTA §1709 (7), Dec. 17, 1992, *available at* http://www.tech.mit.edu/Bulletins/Nafta/00.CONTENTS (last visited May 31, 2005) [hereinafter NAFTA]. *See Evolution of Canadian Law*, *supra* note 76, at *6.

[108] *See* NAFTA, *supra* note 107, §1709 (10) (a); Silbermann, *supra* note 87, at 626.

were met, including: 1) the generic manufacturer seeking a license had unsuccessfully requested authorization from the patent holder on reasonable commercial terms;[109] 2) the license was limited to a specific scope and duration;[110] 3) the use was nonexclusive;[111] and 4) the license terminated when the circumstances that made it necessary ceased or became unlikely to recur in the future.[112] Some Canadians were worried that changing the compulsory license system would cause drug prices to rise.[113]

Despite the changes made in compliance with free trade agreements,[114] Canada still effectively controls the price of patented drugs through the PMPRB.[115] In response to the decreased use of compulsory licenses and the additional requirements of NAFTA, in 1993 the PMPRB received additional authority to regulate patented drug prices.[116] After NAFTA, the powers of the PMPRB increased from simply monitoring prices and using compulsory licenses as a tool for regulating prices, to actually having the power to reduce wholesale prices of patented medicines when they are excessive.[117]

To determine if a price is excessive, the PMPRB compares the drug's price to the median price of the same drug on a specific list of developed nations.[118] These nations are listed in the Patented Medicines Regulations and include France, Germany, Italy, Sweden, Switzerland, the United Kingdom, and the United States.[119] The PMPRB regulates prices continuously and prices cannot increase by more than the Consumer Price Index annually.[120] After an investigation, if the PMPRB finds a price excessive, it can order a price reduction and hold the manufacturer liable for double the excess revenues reaped during the period of the excessive pricing.[121]

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[109] *Id.* §1709 (10) (b). This requirement could be waived in cases of national emergency, extreme urgency, or public noncommercial use. *Id.*

[110] *See id.* §1709 (10) (c).

[111] *See id.* §1709 (10) (d).

[112] *Id.* §1709 (10) (g).

[113] *See NAFTA Threatens Canadian Consumers*, CANADA NEWSWIRE, Feb. 9, 1993, LEXIS, News Group File.

[114] *See* Farolan, *supra* note 88, at 61 ("In order to comply with this [NAFTA] provision, Canada eliminated its compulsory licensing of pharmaceuticals . . . .").

[115] Atkinson, *supra* note 76, at 192.

[116] Carter, *supra* note 78, at 245-46.

[117] PMPRB FAQ'S, *supra* note 80.

[118] *Id.*

[119] *Id.*

[120] *Id.*

[121] ABOUT THE PMPRB, *supra* note 104.

The Canadian PMPRB and the Australian PBS offer a valid comparison to each other. Like the Australian PBS, the Canadian PMPRB protects consumers by ensuring that patented pharmaceuticals are not sold at excessive prices.[122] Unlike the PBS, which lists and prices both patented and generic drugs, the PMPRB's authority over drug prices is limited to patented drugs.[123] The PMPRB sets limits on prices that manufacturers can charge their wholesalers, but, unlike the PBS, it does not set the price at which the drug is sold to consumers.[124] Similar to the PBS, the PMPRB compares the wholesale price to both the price of existing drugs that treat the same disease and the price of the drug in other countries.[125] The main similarity between these two programs is their common overarching goal to ensure access to affordable medicines.

D. Trade Agreements Substantively Changed Canadian Patent Law, But Canada Is Still Able to Ensure Access to Affordable Patented Drugs

The U.S.-Canada Free Trade Agreement and NAFTA substantively changed how Canada provides access to affordable medicines, but they did not undermine Canada's ability to control drug prices. Instead of using compulsory licenses, Canada now uses the PMPRB to ensure access to affordable drugs. Canada's PMPRB ensures that patented drugs are not sold at excessive prices.[126] Nearly every year since the PMPRB was created, the manufacturer's gate prices[127] increased less than the Consumer Price Index.[128] Furthermore, the cost of patented drugs over the past ten years decreased compared to other industrialized nations.[129] Even though NAFTA required stricter patent protection for pharmaceuticals, Canada has been successful in keeping its drug costs down.

Although the powers of the PMPRB increased because of NAFTA, the PMPRB is still not as comprehensive as the PBS in providing access to affordable medicines because it does not regulate prices of generic

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[122] *Id.*

[123] Carter, *supra* note 78, at 247.

[124] PMPRB FAQ's, *supra* note 80.

[125] *Id.*

[126] *See* JOHN R. GRAHAM, THE FRASER INSTITUTE, PRESCRIPTION DRUG PRICES IN CANADA AND THE UNITED STATES—PART 2: WHY THE DIFFERENCE? (Sep. 2000) *available at* http://www.fraserinstitute.ca/shared/readmore.asp?sNav=pb&id=161 (last visited May 31, 2005).

[127] *See* Price Control Report, *supra* note 1 (describing how the PMPRB caps act as a ceiling and even lowers prices). A gate price is the price at which the manufacturer sells to wholesalers, hospitals, or pharmacies. *See* ABOUT THE PMPRB, *supra* note 104.

[128] GRAHAM, *supra* note 126.

[129] PMPRB FAQ'S, *supra* note 80.

medicines.[130] The substantive changes to Canadian law were more significant than the changes to the PBS, suggesting that the PBS is more likely to continue controlling drug prices.

IV. THE U.S.-AUSTRALIA FREE TRADE AGREEMENT WILL NOT SIGNIFICANTLY IMPACT AUSTRALIAN PATENTED DRUG PRICES

In comparison to the substantive changes that the Canadian trade agreements provoked in Canadian patent and licensing laws, the U.S.-Australia FTA resulted in minor procedural changes to the PBS. These changes should not significantly impact Australian drug prices. The Australian government has stated that most of the provisions in the U.S.-Australia FTA agreement dictate practices that PBAC already follows when it considers listing a new medication.[131] The U.S.-Australia FTA addresses pharmaceuticals in its Annex 2-C, which outlines Agreed Principles, Transparency, Medicines Working Group, Regulatory Cooperation, and Dissemination of Information.[132] None of these categories, or their subparts, compels the elimination of the PBS, or even hinders its effectiveness. In fact, some of the principles will improve the efficiency of the PBS.

The U.S.-Australia FTA provisions regarding transparency focus on making the PBS process for listing and pricing more transparent and expeditious for an applicant.[133] The U.S.-Australia FTA requires procedures that protect patents by preventing a generic drug manufacturer from marketing during the patent term and requires the generic drug manufacturer to provide notice to the patent holder when it intends to challenge a patent.[134] These measures do not change a generic drug manufacturer's ability to

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[130] *Id.*

[131] AUSTRALIAN GOVERNMENT DEPARTMENT OF FOREIGN AFFAIRS AND TRADE, AUSTRALIA-UNITED STATES FREE TRADE AGREEMENT BACKGROUNDERS, THE AUSTRALIA-UNTIED STATES FREE TRADE AGREEMENT: PHARMACEUTICAL BENEFITS SCHEME (PBS) OUTCOMES, *available at* http://www.dfat.gov.au/trade/negotiations/us_fta/backgrounder/pbs.html (last visited May 31, 2005; copy on file with Journal) [hereinafter PBS OUTCOMES]. Mark Vaile, the Australian Minister for Trade, has further declared that "the detail[s] of implementation remains at Australia's discretion—not America's—thus protecting the PBS." Media Release, The Honorable Mark Vaile, MP, Minister for Trade, The AUSFTA, PBS and Access to Medicines, May 21, 2004, at http://www.trademinister.gov.au/releases/2004/mvt036_04.html (last visited May 31, 2005).

[132] United States-Australia Free Trade Agreement, May 18, 2004, U.S.-Austl., Annex 2-C §§ 1-5, *available at* http://www.ustr.gov/Trade_Agreements/Bilateral/Australia_FTA/Final_Text/Section_Index.html (last visited May 31, 2005) [hereinafter Annex 2-C].

[133] *See* Economic Analysis, *supra* note 21.

[134] USTR, SUMMARY OF THE U.S.-AUSTRALIA FREE TRADE AGREEMENT, FREE TRADE "DOWN UNDER" (Feb. 8, 2004), *available at* http://www.ustr.gov/Document_Library/Fact_Sheets/2004/Summary_of_the_U.S.-Australia_Free_Trade_Agreement.html (last visited May 31, 2005).

springboard.[135] The continued existence of the PBS and Australia's power to interpret the provisions of the U.S.-Australia FTA will ensure drug prices remain low for Australians.

A. The Agreed Principles Do Not Change How the PBS Operates

The four Agreed Principles of the U.S.-Australia FTA reflect a compromise between the two nations' market philosophies: universal access versus competitive access. The first principle states that innovative pharmaceuticals play an important role in delivering high-quality health care.[136] The pharmaceutical programs of both nations reflect this principle, even though each nation approaches delivery differently. The second principle pronounces the important role of research and development in creating new medicines and calls for appropriate government support such as intellectual property protection.[137] In the third principle, the nations agreed upon a need for "transparent, expeditious and accountable procedures" in order to promote timely and affordable access to innovative medicines.[138] These procedures should not impede either nation's ability to enforce its appropriate standards of quality, safety and efficacy. Finally, the fourth principle is an explicit acceptance of both market philosophies. It declares the need to value innovative pharmaceuticals either by competition (as in the United States), or by procedures that place a value on the therapeutic significance of the drug (as in Australia through the PBS).[139] The principles themselves do not eliminate or otherwise destroy the basis of the PBS. In fact, the fourth principle explicitly affirms the PBS's role.[140]

B. The U.S.-Australia FTA Primarily Made Procedural Changes to the PBS

Unlike the substantive changes to Canadian patent law under its free trade agreements, the changes produced by the U.S.-Australia FTA in Australia are less significant because they are merely procedural. The changes to the PBS are enumerated under the Transparency section of Annex 2-C of Chapter 2, National Treatment and Market Access for Goods, of the

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[135] PBS & AUSFTA, *supra* note 22.

[136] *See* Annex 2-C, *supra* note 132, §1(a).

[137] *Id.* §1(b).

[138] The Transparency section of the FTA expounds on this principle and will be discussed in more detail in Part IV.B *infra*.

[139] Annex 2-C, *supra* note 132, §1(d).

[140] *Id.*

U.S.-Australia FTA[141] and in side letters to the agreement.[142] The transparency provisions apply to federal healthcare authorities that list pharmaceuticals or set reimbursement rates for them.[143] Since the United States does not have a federal program that performs this function,[144] the provisions apply only to Australia's PBS. The side letters make this clear.[145]

All of the transparency provisions require certain procedural safeguards and focus on making the program operate with "transparent, expeditious, and accountable procedures."[146] To expedite the process of listing with the PBS, the first provision calls for PBAC to review drug sponsors' applications within a "specified time."[147] A PBAC report released in July 2004, outlined recommendations that would reduce the time it takes for a drug to be listed with the PBS.[148] This means consumers will have access to medicines faster—a benefit to Australians.[149] This will also benefit manufacturers because they will be able to sell their product sooner. This provision of the U.S.-Australia FTA does not result in price increases or decreased access to medicines.

The next set of provisions aims to increase transparency by requiring the disclosure of "procedural rules, methodologies, principles and guidelines" that the PBS uses in reviewing applications.[150] PBAC reviews applications on a case-by-case basis without distinction to whether the drug

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[141] *Id.* §2;

[142] Letter from The Honorable Robert B. Zoelick, United States Trade Representative, to The Honorable Mark Vaile, Minister of Trade (May 18, 2004), *available at* http://www.ustr.gov/assets/Trade_Agreements/Bilateral/Australia_FTA/Final_Text/asset_upload_file840_3886.pdf [hereinafter Letter from Zoelick]. The letter explains that both governments consider the letter "an integral part of the Agreement." *Id.*

[143] Annex 2-C, *supra* note 132, §2.

[144] *See supra* note 8, and accompanying text.

[145] Letter from Zoelick, *supra* note 142.

[146] Annex 2-C, *supra* note 132, §1(c).

[147] A specific timeframe was not determined by the FTA. In the first post-FTA Policies, Procedures, and Methods Manual of the Pricing Authority, the timeframe for listing and pricing was established as four months for the PBAC and five months for the Pricing Authority, for a total of nine months. *See* PHARMACEUTICAL BENEFITS PRICING AUTHORITY POLICIES PROCEDURES AND METHODS USED IN THE PRICING OF PHARMACEUTICAL PRODUCTS (Jan. 24, 2005), *available at* http://www.health.gov.au/internet/wcms/publishing.nsf/Content/health-pbs-general-pricing-pbpamethods.htm/$FILE/pbpamethods.pdf (last visited May 31, 2005) [hereinafter PRICING AUTHORITY POLICIES].

[148] DEPARTMENT OF HEALTH AND AGEING, NEW PBS MEDICINES AVAILABLE FASTER: REPORT PLAN, *available at* http://www.health.gov.au/internet/wcms/publishing.nsf/Content/health-mediarel-yr2004-ta-abb122.htm (last visited May 31, 2005) (claiming that the timeframe, which was five months at the time of the report, will be significantly reduced).

[149] *See* DEPARTMENT OF FOREIGN AFFAIRS AND TRADE, AUSTRALIA-UNITED STATES FREE TRADE AGREEMENT, GUIDE TO THE AGREEMENT, *available at* http://www.dfat.gov.au/trade/negotiations/us_fta/guide/2.html (last visited May 31, 2005).

[150] Annex 2-C, *supra* note 132, §2(b).

is essential or non-essential.[151] By forcing the disclosure of the criteria for review, this U.S.-Australia FTA provision will enable applicants to present relevant information in the best way possible. This, in turn, will assist the PBAC in making its decision and creating a more efficient process. Furthermore, applicants will be provided detailed written information regarding the basis for PBAC and Pricing Authority decisions.[152] Although the Pricing Authority has already released its decision-making criteria,[153] the detailed report describing the basis for the listing and pricing decisions will be helpful to the applicant and will also improve efficiency.

A more substantial change, but still only a procedural one, is a new independent review process mandated by the U.S.-Australia FTA that will benefit the applicant and the public.[154] This process provides for a review, independent of the PBS and by a new entity, of adverse PBAC listing determinations, upon request from the drug's sponsor.[155] This review process will provide the sponsor with more information about the PBAC decision, including a detailed explanation of the PBAC's reasoning in rejecting the sponsor's application.[156] The U.S.-Australia FTA does not make the review process binding, but it does provide an opportunity for the manufacturer to provide additional input during the drug's assessment and subsequent recommendation to the Pricing Authority.[157] This will increase transparency of the PBS process of listing and pricing a drug because the reasoning behind PBAC decisions will become publicly available.[158] The Australian Department of Health and Ageing ("Department") released details regarding its implementation of this new review process on February 4, 2005.[159] In the release, the Department asserted that the PBS will not only keep drug prices low, but will be "more accountable and transparent for all

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[151] *See* RICKARD, *supra* note 2. "PBAC does not employ any formal definitions or criteria for the distinction." *Id.*

[152] Annex 2-C, *supra* note 132, §2(d).

[153] *See* PRICING AUTHORITY POLICIES, *supra* note 147.

[154] Annex 2-C, *supra* note 132, §2(f).

[155] Letter from Zoelick, *supra* note 142.

[156] *See* Economic Analysis, *supra* note 21; PBS & AUSFTA, *supra* note 22.

[157] PBS & AUSFTA, *supra* note 22.

[158] *See* Media Release, The Honorable Mark Vaile, MP, Minister for Trade, Australia-United States FTA No Threat to PBS (July 25, 2004), *available at* http://www.trademinister.gov.au/releases/2004/mvt064_04.html (last visited May 31, 2005); Annex 2-C, *supra* note 132, §2(e) (noting that the confidential information of the application will be protected from the public).

[159] AUSTRALIAN GOVERNMENT DEPARTMENT OF HEALTH AND AGEING, AUSTRALIA-UNITED STATES FREE TRADE AGREEMENT AND THE PHARMACEUTICAL BENEFITS SCHEME (Feb. 4, 2005), *available at* http://www.health.gov.au/internet/wcms/publishing.nsf/Content/health-mediarel-yr2005-ta-abb008.htm (last visited May 31, 2005) [hereinafter FTA AND THE PBS].

stakeholders in the PBS."[160] Thus, the Transparency provision will benefit not only the applicants, but also the public.

Secondly, in order to enhance transparency, meaningful consultation, and accountability of the PBS, the U.S.-Australia FTA provides for opportunities for the applicant to interact with the PBS on four points:

> (a) an opportunity to consult relevant officials prior to submission of an application for listing, including on the selection of a comparator pharmaceutical; (b) an opportunity to respond fully to reports or evaluations relating to the applications that are prepared for the technical subcommittees of the [PBAC]; (c) an opportunity for a hearing before PBAC while it is considering reports or advice from the technical subcommittees to the PBAC regarding applications; and (d) sufficient information on the reasons for PBAC's determination on an application, on an expeditious basis, to facilitate any application to the [Pricing Authority].[161]

These opportunities are valuable because they will facilitate communication between an applicant and the PBS. The applicant will have opportunities to discuss the application throughout the PBS process, and PBS will be able to obtain more accurate and complete information. This may lead to a more efficient PBS.

Unlike the Canadian trade agreements provisions, which focused on changing substantive laws of Canada, the provisions of the U.S.-Australian FTA require merely procedural changes aimed at improving communication. Importantly, although there are increased opportunities for applicants to offer more information to the PBS, the U.S.-Australia FTA did not change the criteria by which the Pricing Authority evaluates new drugs.[162] Further, the transparency provisions serve only to supply PBS decision makers and the public with information consistent with the pre- U.S.-Australia FTA review criteria.

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[160] *Id.*

[161] Letter from Zoelick, *supra* note 142.

[162] *Compare* PBPA ANN. REP., *supra* note 53, at 4 ("Factors considered by the Authority" lists factors a-i), *with* PRICING AUTHORITY POLICIES, *supra* note 147, at 8 ("Factors Considered by the Pricing Authority" lists same factors a-i).

C. *Australian Consumers Will Continue to Enjoy Timely Access to Generics*

The U.S.-Australia FTA created minor changes to intellectual property rights of drug manufacturers, but Australian consumers will still have timely access to generics.[163] Before the U.S.-Australian FTA, a generic drug applicant had to wait five years from the patented drug's original approval date before applying to the Therapeutic Goods Administration for marketing approval.[164] This delay was called the data exclusivity period.[165] Before the U.S.-Australia FTA, the Therapeutic Goods Administration did not consider the status of a patent when reviewing the generic drug applicant.[166] The generic drug manufacturer was permitted to complete the steps for listing and pricing before the patent expired, but was not allowed to actually manufacture the drug while the patent was still in effect.[167] In some circumstances, however, the generic drug producer decided to manufacture and enter the market before the patent expired to see if the patent holder would take action.[168] In such a case, the generic drug producer could challenge the patent or argue that there was no infringement, but it would have already entered the market and infringed on the patent holder's rights. The U.S.-Australia FTA made a small change to this process that somewhat favors the patent holder.

Before the U.S.-Australia FTA, a generic drug producer could apply to springboard and get marketing approval from the Therapeutic Goods Administration by using the patent holder's test data.[169] This continues to be true after the U.S.-Australia FTA. Before the U.S.-Australia FTA, the Therapeutic Goods Administration did not consider the status of the patent when reviewing the generic drug applicant.[170] This has changed. The generic drug applicant must meet a new certification requirement.[171] To meet the certification measure, the generic drug manufacturer must either: (1) attest that it reasonably believes that it does not and will not market in a

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[163] PBS & AUSFTA, *supra* note 22.

[164] TYACKE, *supra* note 64.

[165] PBS & AUSFTA, *supra* note 22.

[166] *Id.*

[167] *See* Christine Wallace & Roy Eccleston, *US Using FTA in Backdoor Attempt to Wind Back Generic Drugs*, THE AUSTRALIAN, Dec. 18, 2003 at 2; Moscaritolo & Starick, *supra* note 70.

[168] PBS & AUSFTA, *supra* note 22.

[169] *See supra* Part II.C.

[170] *Id.*

[171] United States-Australia Free Trade Agreement, May 18, 2004, U.S.-Austl., § 17.10.4, *available at* http://www.ustr.gov/Trade_Agreements/Bilateral/Australia_FTA/Final_Text/Section_Index.html (last visited May 31, 2005).

manner that would infringe on the patent holder's rights, or; (2) attest that the applicant intends to market before the patent expires, but has given notice to the patent holder of their PBS application.[172] Once the generic drug manufacturer certifies that it has met one of these options, it can take advantage of the original applicant's research and test data proving its safety, efficacy, and quality.[173]

Some fear that the new certification process opens the door to litigation between the patent holder and the generic drug applicant, leading to a delay in generics reaching the market and an increase in the costs of pharmaceuticals to consumers.[174] However, this is unlikely. The requirement of the certification process is similar to the "notice of compliance" ("NOC") that Canada implemented.[175] It essentially requires the applicant to either agree that the drug has a legitimate outstanding patent holder, or notify the patent holder of its belief that infringement on the patent holder's rights will not occur.[176] The NOC process determines the status of the relevant patents before a generic drug manufacturer infringes on the patent holder's rights.[177] Similarly, the new certification process in Australia is an easy step for a generic drug manufacturer to meet, and can help avoid litigation by obtaining a determination of the patent status before infringement occurs.

D. The New Medicines Working Group Has No Impact on the PBS

The U.S.-Australia FTA calls for the formation of a new bilateral Medicines Working Group.[178] This Working Group will discuss issues relating to pharmaceuticals and the U.S.-Australia FTA provisions that relate

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[172] *See* AUSTRALIAN GOVERNMENT DEPARTMENT OF HEALTH AND AGEING, AMENDMENTS TO THE THERAPEUTIC GOODS ACT 1989, *available at* http://www.tga.gov.au/international/usfta.htm (last visited May 31, 2005). *See also* AUSTRALIAN GOVERNMENT DEPARTMENT OF HEALTH AND AGEING, CERTIFICATION IN RELATION TO PATENTS, *available at* http://www.tga.gov.au/international/usftacert26b.pdf (last visited May 31, 2005) (the approved form for subsection 26(B)1 of the Therapeutic Goods Act 1989).

[173] PBS & AUSFTA, *supra* note 22.

[174] *Id. See also* Peter Drahos, *Our PBS Bill Will be Higher if FTA Goes Ahead*, CANBERRA TIMES, May 31, 2004, at 12 (quoting the Generic Medicines Industry Association and alleging that FTA provisions may "delay rapid generic entry on to the PBS and drive up its costs to the taxpayers").

[175] *See Evolution of Canadian Law*, *supra* note 76, at *10-15 (explaining that the Notice of Compliance was implemented in the same legislation as the other NAFTA changes).

[176] *See* Anita Nador & Melanie Szweras, *Comparing Canadian Notice of Compliance (NOC) Regulations for Patented Medicines with Corresponding United States and European Union Provisions* (Mar. 4, 2002), *available at* http://www.bereskinparr.com/publications/art_html/bio-noc-regul-nador.html (last visited May 31, 2005).

[177] *See id.*

[178] Annex 2-C, *supra* note 132, §3.

to pharmaceuticals.[179] Appropriate government officials will serve on the Working Group.[180] The skepticism surrounding the Working Group is based on the lack of details about its operation.[181] What is important, however, is that the Working Group is similar to other inter-party groups created under the U.S.-Australia FTA and therefore is not a policy making body, but rather a discussion forum.[182] This forum may allow the parties to avoid disputes concerning the U.S.-Australia FTA by discussing interpretations in the Working Group.

Similarly, under the provisions for Regulatory Cooperation, the U.S.-Australia FTA calls for existing dialogue to continue between the two nations' regulatory arms that review the safety and efficacy of pharmaceuticals—the Therapeutic Goods Administration and the U.S. Food & Drug Administration.[183] This dialogue has "a view to making innovative medical products more quickly available to their nationals."[184] This does not imply that the PBS is in jeopardy because the Food & Drug Administration and Therapeutic Goods Administration have already engaged in discussion, and consumers from both nations benefit from the discussions, which aim to make medicines available sooner. The concern of some Australians, however, is that the requirement of the dialogue implies that research and development are more important than affordable access (assuming that research and development enable quick availability of innovative medicines). The Therapeutic Goods Administration can counter that interpretation of the requirement for inter-agency dialogue by stressing the importance of financial access once the medicines have been developed. Research and development is part of what makes innovative medicines physically available to consumers, but availability includes economic access, which is dependent on the affordability of medicines. Hence, this part of the U.S.-Australia FTA should not hinder the PBS in meeting its mission.[185]

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[179] *Id.* §3(b).

[180] *See* PBS OUTCOMES, *supra* note 131.

[181] *See* DEPARTMENT OF FOREIGN AFFAIRS AND TRADE, *supra* note 149, at *5 (noting that details concerning how it will operate and how often it will meet have not been decided). *See also* Ken Harvey, *Pharmaceutical benefits and free trade: trouble ahead for subsidised medicines in Australia*? (Mar. 19, 2004), *available at* http://www.econ.usyd.edu.au/drawingboard/digest/0403/harvey.html (last visited May 31, 2005) (discussing that the United States and Australia have different views of the working group which causes concerns).

[182] *See* PBS OUTCOMES, *supra* note 131; Harvey, *supra* note 181.

[183] Annex 2-C, *supra* note 132, §4.

[184] *Id.*

[185] The final clause in the FTA concerns the dissemination of information. *Id.* §5. It did not change any Australian laws. *See* PBS OUTCOMES, *supra* note 131.

E. The Continued Authority of the PBS and the Influence of Australian Public Opinion Will Ensure That the Price of Medicines Will Not Be Significantly Impacted by the U.S.-Australia FTA

The continued existence of the PBS, combined with the Australian people's sense of entitlement to affordable medicines, will keep pharmaceutical prices low. The PBS, like the Canadian PMPRB, is intended to keep down the prices of patented medicines.[186] Unlike the PMPRB, the PBS has power to negotiate prices for generic drugs and set consumer prices for all pharmaceuticals.[187] As is the case with the PMPRB in the post-NAFTA years, the PBS will successfully control pharmaceutical prices post-U.S.-Australia FTA. Several factors support this prediction.

First, the U.S.-Australia FTA did not dismantle the PBS, change how it lists or prices drugs, or diminish its power to do so.[188] The PBS still considers the therapeutic value of a drug in setting prices.[189] The PBS does not focus on the cost of developing a drug, but instead on what it is worth to its citizens.[190] The subsidization program dismisses research and development costs when it sets prices.[191] As long as the program exists, and as long as drugs are subsidized, drug manufacturers will continue to seek subsidization and perpetuate the power of the PBS to control prices. In order to compete in the artificial Australian market, the drug must have an artificial price—a subsidized price.

Second, the Australian government and citizens are too protective of the PBS to allow the U.S.-Australia FTA to materially alter its program or benefits. During the negotiations of the U.S.-Australia FTA, the Australian citizens were particularly vocal in their support for protecting the power of the PBS to regulate drug prices.[192] For example, one group, comprised of representatives from more than two dozen leading medical, legal, health, and community services organizations, sent a twenty-six page document to Prime Minister John Howard and Mark Latham, the Federal Labour Party Leader, claiming that the U.S.-Australia FTA would allow U.S. drug companies to challenge the PBS, and demanding changes to the

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[186] *See supra* Part II.A.

[187] *Compare* PBS & AUSFTA, *supra* note 22, *with* Carter, *supra* note 78, at 247.

[188] *See* FTA AND THE PBS, *supra* note 159.

[189] *See* PRICING AUTHORITY POLICIES, *supra* note 147, at 8.

[190] *Id.*

[191] *Id.*

[192] Despite the concerns, the Australian government remained confident that the FTA would not impact the PBS. *See, e.g.*, Economic Analysis, *supra* note 21 (discussing how the PBS was not included in the economic impact study because the government believes the FTA will not impact the PBS or the price of drugs in Australia).

agreement.[193] Another letter, signed by 380 academics from across Australia, demanded more honesty and independence from the government.[194] The concerns over the U.S.-Australia FTA ranged from dispute resolution to generic drug entry, and from drug companies ending research and development of drugs in Australia to rising drug prices.[195] This public outcry did not go unnoticed by the Australian government. In fact Prime Minister Howard, nervous about re-election, responded to the pressure by pushing through parliament a change to the U.S.-Australia FTA enabling legislation that was later amended to comply with the U.S.-Australia FTA.[196]

V. CONCLUSION

Although there are ongoing concerns that the United States-Australia Free Trade Agreement may adversely impact prices of pharmaceuticals in Australia, the U.S.-Australia Free Trade Agreement requirements will not significantly affect the pricing scheme. As in Canada, where the Patented Medicine Prices Review Board effectively limits the price of patented pharmaceuticals in the years since NAFTA was implemented, the Pharmaceutical Benefits Scheme in Australia will likely be able to effectively manage the price of drugs for its citizens in the post-U.S.-Australia Free Trade Agreement era. The changes the United States trade agreements made to the Canadian system were more significant than the changes the U.S.-Australia Free Trade Agreement requires of Australia, and Canada has been able to keep prices under control. The public support in Australia for the Pharmaceutical Benefits Scheme will continue to play an important role in its power to list and price innovative drugs.

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[193] Pirani, *supra* note 45.

[194] *Id.*

[195] *See, e.g., id.*; Drahos, *supra* note 174 (expressing concern that generic drugs will be delayed); Australian Associated Press, *Australia May Bow to Drug Firm's Demands*, Oct. 22, 2004, LEXIS, Nexis Library, News Group File (discussing how the aim to keep drug prices low may be undermined by the lobbying efforts of the pharmaceutical companies); Drug Prices to Rise Under FTA, SBS NEWS MEDIA, Jul. 22, 2004, *available at* http://www9.sbs.com.au/theworldnews/region.php?id=89863&region=7 (last visited May 31, 2005) (reporting that an Australian National University report says drug prices will rise under the agreement); Kevin Outterson, *Free Trade in Pharmaceuticals* (Jul. 25, 2004), *available at* http://www.mja.com.au/public/rop/ausfta/out10366_fm.html (last visited May 31, 2005) (generally arguing that the focus of the FTA is on pharmaceutical companies rather than consumers and may harm the PBS); Frenkel *supra* note 14, at 5 (alleging that consumers as taxpayers or patients will have to pay more because of the new independent review process and the Medicines Working Group).

[196] *See* Press Release, USTR, Landmark U.S.-Australia Free Trade Agreement Goes Into Effect Today (Jan. 1, 2005), http://www.ustr.gov/Document_Library/Press_Releases/2005/January/Lmark_U.S.-Australia_Free_Trade_Agreement_Goes_Into_Effect_Today.html (describing that although Australia had passed implementing legislation in August 2004, it had to pass more legislation in December 2004 to meet the intellectual property provisions of the FTA).