THE HON TONY ABBOTT MP
MINISTER FOR HEALTH AND AGEING
Leader of the House of Representatives

Australia - United States Free Trade Agreement (AUSFTA)

Implementation of the Obligations to Improve Transparency of the Pharmaceutical Benefits Scheme (PBS)

through

An Independent Review Mechanism,

Hearings before the Pharmaceutical Benefits Advisory Committee (PBAC)

and

Transparency of Decision Making

Public Consultation Document

25 July 2004

Introduction

The Free Trade Agreement signed by Australia and the United States (AUSFTA) in May 2004 included commitments relating to federal health care programs dealing with the reimbursement of prescription medicines. These were articulated in Annex 2C (Pharmaceuticals) to Chapter 2 - National Treatment and Market Access for Goods. In an associated Exchange of Letters, Australia made a number of additional commitments to the United States. The relevant texts are at Appendix A.

Throughout the negotiation of the AUSFTA the Australian Government vigorously defended the fundamental architecture of the Pharmaceutical Benefits Scheme (PBS) and the integrity of the Pharmaceutical Benefits Advisory Committee (PBAC) as the pre-eminent advisory body to government on the listing of medicines on the PBS. The *National Health Act 1953* states that the Minister for Health and Ageing may only add to the PBS medicines recommended for listing by the PBAC. Consistent with this, no changes to the Act are necessary to implement Australia's AUSFTA commitments.

Since the conclusion of the Agreement the Government has become aware that a particular concern within the Australian community has been the potential impact on the PBS of the commitment to establish an independent review of recommendations made to Government by PBAC. This was one of a range of measures agreed to enhance the transparency and accountability of the operation of the PBS. For many Australians this issue has emerged as a key test of whether the AUSFTA satisfactorily protects the integrity of the PBS.

The Government is confident that the commitments it has made will have no adverse impact on the sustainability of the PBS. On the contrary, the independent review mechanism, together with other transparency measures agreed under the AUSFTA, will deliver improvements in the transparency of the PBS which will be of benefit to the pharmaceutical industry, prescribers, consumers and taxpayers.

In June 2004 the Minister for Health and Ageing established a working group to advise him on a way forward for the implementation of these commitments. The working group comprises members of the Pharmaceutical Benefits Advisory Committee, Medicines Australia and a consumer representative. This position paper has been developed from the advice of that working group.

Three key issues were identified by the Minister as requiring detailed consideration by the working group. These were i) the design of the independent review mechanism for PBAC recommendations; ii) providing opportunities for hearings before PBAC and iii) improvements in transparency of PBAC processes and decision-making.

This paper will be available on the Department of Health and Ageing website from Monday 26 July 2004. To allow views to be taken into account comments should reach the Department of Health and Ageing by 20 August 2004. If you would like to register your views on the issues addressed in this paper you should either write to:

AUSFTA Contact Officer,
Pharmaceutical Benefits Branch
MDP 83
Department of Health and Ageing
PO Box 9848
Canberra Act 2601

or go to www.health.gov.au/ausfta

1. Independent Review Mechanism

In the interests of greater transparency and accountability, Australia has agreed to establish a review mechanism that will be made available to an applicant when an application to have a drug added to the PBS has not resulted in a PBAC recommendation to list.

The relevant AUSFTA text is Annex 2-C which requires the Parties to:

> *… make available an independent review process that may be invoked at the request of an applicant directly affected by a recommendation or determination.*

This is clarified in the associated Exchange of Letters that states that:

> *Australia shall provide an opportunity for independent review of PBAC determinations, where an application has not resulted in a PBAC recommendation to list.*

It is proposed that the independent review mechanism should operate as set out below.

Guiding Principles

The independent review process will be independent of the applicant, the PBAC and of the staff or contractors of the Department of Health and Ageing involved in any prior evaluations of the drug for the indication(s) requested.

An independent review may only be sought by an applicant – that is the sponsor of the application to the PBAC.

Independent review will only be made available where an application to the PBAC has not resulted in a recommendation to list.

A convenor will be appointed to manage the independent review function. The convenor will not conduct the review but will appoint a reviewer from a list of identified experts.

The reviewer may seek clarification of the information available by discussion with the applicant or the PBAC or the Department of Health and Ageing, as arranged through the convenor. Following consultation with the convenor the reviewer may also consult, as appropriate, with other relevant experts.

Any consultations relating to the conduct of the independent review will be conducted in closed session.

The outcomes of the independent review will be made publicly available in a similar timeframe to the publication of outcomes from PBAC meetings.

The timeline for the conduct of the independent review will be such that it involves no additional delay in the PBS processes. There should be no time incentive, or disincentive, for applicants to seek a review in preference to making a resubmission to PBAC.

The findings of the independent review will be reported to the PBAC.

After consideration by the PBAC, the review findings and the outcome of PBAC's reconsideration of the submission in light of the findings of the review will be reported to the Minister for Health and Ageing within 15 days of the PBAC's consideration.

Applicants will retain the option to resubmit to the PBAC if additional data or information subsequently become available, but a resubmission will not be accepted while a review is in process.

Operation of the Independent Review

Management of the independent review process will be undertaken by a permanently appointed convenor. The convenor's role will be to ensure the integrity and efficient operation of the review process.

Individual reviews will be conducted by a reviewer, selected from a panel of experts including, but not limited to, medical specialists, epidemiologists, pharmaco-epidemiologists, health economists, clinical pharmacologists, biostatisticians, and clinical trials experts.

The applicant seeking a review will identify those issues that are in dispute and the review will focus on these issues. The issues must reflect the PBAC's reasons for rejection of the application. The convenor will consider the issues in dispute in appointing an appropriate reviewer. The reviewer must not be an employee or member of the evaluation group that undertook the initial evaluation of the application to the PBAC.

The reviewer will be an individual whose qualifications and expertise are relevant to the key issue(s) under review.

When there are disparate issues in contention, the reviewer may seek advice as required after consultation with the convenor. Any person consulted would be identified in the reviewer's report. The reviewer and all people consulted during a review will be required to lodge conflicts of interest statements with the convenor.

The review will have access to all the information placed before the PBAC by the applicant, as well as the deliberations of the PBAC and its sub committees on the application. No new data are to be provided to the reviewer.

The independent review process will be evaluated after 12 months of operation to ensure that it is meeting the objectives of accountability and transparency and is workable for all concerned.

Conduct of the review

The applicant will put a request for a review to the convenor in writing, and provide a statement outlining the issues about which the review is sought.

The convenor will notify the applicant and the PBAC the name of the reviewer selected to conduct the review.

The appointed reviewer must declare to the convenor any real or potential conflicts of interest. The convenor will ensure that the reviewer has the credentials to be fair and impartial in conducting the review.

The reviewer shall take into consideration all available documents, information and other written material available to PBAC, including documents, information and material relating to the issues in dispute and to arguments and submissions upon the matters under consideration. However no new data will be accepted, beyond that previously made available to the PBAC.

A review should be completed in a timeframe that allows the reporting back to the PBAC meeting in the same timeframe as a resubmission.

The convenor will lodge the reviewer's report to the PBAC with the PBAC secretariat no later than 4 weeks before the PBAC meeting at which the matter will be considered, and at the same time provide copies to the applicant.

The applicant will be invited by the PBAC Secretariat to provide a pre-PBAC response to the reviewer's report.

Confidential information will be afforded the same level of protection as information put to the PBAC.

A proposed timeline for the conduct of the independent review is at Attachment 1.

Management of reviews

Criteria for selection of convenor

The following criteria are proposed for the selection of the convenor of the independent review mechanism:

- Substantial experience at a senior level in industry, commerce, public administration, academe, a profession or the public service;
- Knowledge of public administration together with experience in health care matters;
- Demonstrated commitment to impartiality and objectivity and evidence of standing and respect within the community;
- Free of actual or perceived conflicts of interest;
- Strong communication skills.

Duties and responsibilities of the convenor

The following duties and responsibilities are proposed for the convenor of the independent review mechanism:

- Management of the review process including liaison with the parties and maintenance of its independence;
- Identification and maintenance of a panel of experts;
- Facilitation of selection of experts for particular reviews;
- Oversight and implementation of rules and procedures relating to reviews;
- Monitoring outcomes, adherence to rules, procedures and ethical standards;
- Periodic (annual) reporting on the review process to the Government.

It is recommended that it be the responsibility of the convenor to ensure at the time of nomination of reviewer of an application that reviewers do not have a real or perceived conflict of interest.

Criteria for selection of expert panel members

The single mandatory criterion for selection of expert panel members is recognised expertise in a relevant discipline. Relevant disciplines include:

- Clinical pharmacology
- Epidemiology
- Pharmacoepidemiology
- Health economics
- Biostatistics
- Internal medicine subspecialties

2. Hearings before PBAC

Under the AUSFTA Australia agreed to provide enhanced transparency to ensure meaningful consultation and accountability in PBS processes. The relevant provisions in the AUSFTA Exchange of Letters include the undertaking that:

> *In order to ensure transparency, … Australia shall provide … the opportunity for a hearing before the PBAC while it is considering reports or advice from the technical subcommittees to the PBAC regarding its application.*

The process currently allows for a number of "contact points" between the sponsor companies and the PBAC process, including:

- Pre-submission meetings with staff of the Department of Health and Ageing;
- Provision of written responses to departmental reports;
- Provision of written responses to PBAC sub-committee reports;
- Following a rejection of an application for listing, discussion with departmental staff and PBAC Chair to facilitate re-submission.

To provide opportunities for hearings before PBAC, it is proposed that:

- To avoid the process becoming unworkable, hearings before PBAC should be confined to specific issues and limited in scope, duration and frequency;
- Consideration could be given to hearings before the PBAC's technical sub-committees to address concerns about clinical or economic issues, and/or predictions for utilisation of a proposed drug;
- Medicines Australia will develop a code of practice to guide applicants in the most appropriate circumstances for seeking a hearing before PBAC;
- Throughout the PBAC process contact officers in the Department of Health and Ageing could enhance dialogue, including, where necessary, by liaising between the applicant and the evaluation process.

3. Transparency Principles

Consistent with National Medicines Policy, which states that consumers and health practitioners should be encouraged to understand the costs, benefits and risks of medicines, the working group acknowledges that all stakeholders in the PBS have a right to be informed about the basis of the PBAC's recommendations.

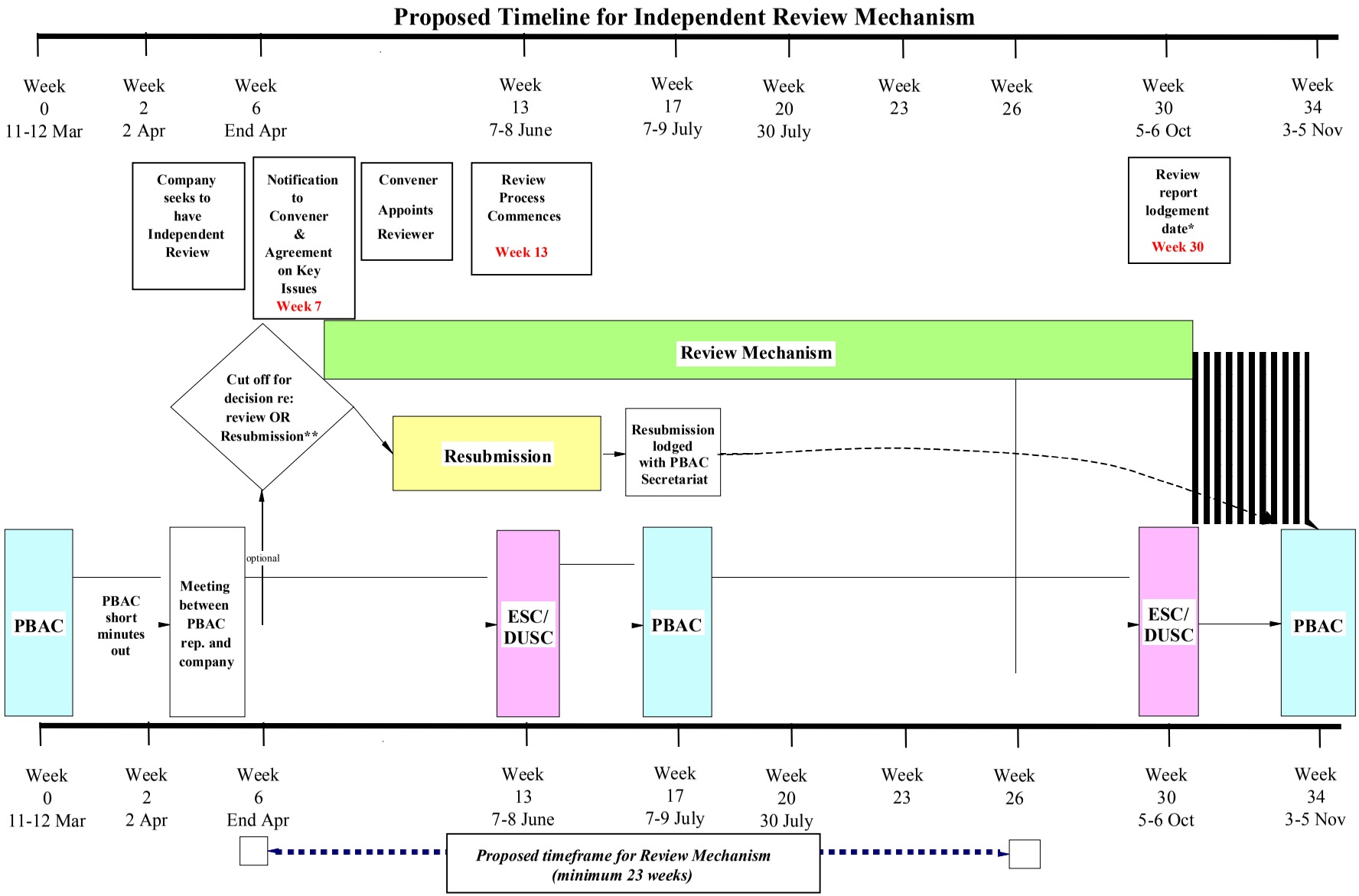
Expanding information currently made publicly available in accordance with the principles below will facilitate better understanding of the operation of the PBS and promote a shared commitment to its sustainability. Such information should include all aspects of PBAC considerations, including those of the independent review.

To that end the following principles are proposed:

- Details of all recommendations made by the PBAC should be available to the public in a timely manner following each PBAC meeting;
- The information should include the relevant clinical, economic and utilisation data justifying PBAC's recommendations;
- Material agreed as confidential should be protected.

The Minister for Health and Ageing has agreed to the working group's request for additional time to develop a detailed proposal that reflects these principles, including the mechanism by which consultation regarding the release of these materials will be undertaken. This proposal will be informed by the public response to this position paper.

Attachment 1



** intention is that companies will not be able to pursue both options simultaneously

Appendix A

ANNEX 2-C

PHARMACEUTICALS

1. AGREED PRINCIPLES

The Parties are committed to facilitating high quality health care and continued improvements in public health for their nationals. In pursuing these objectives, the Parties are committed to the following principles:

(a) the important role played by innovative pharmaceutical products in delivering high quality health care;

(b) the importance of research and development in the pharmaceutical industry and of appropriate government support, including through intellectual property protection and other policies;

(c) the need to promote timely and affordable access to innovative pharmaceuticals through transparent, expeditious, and accountable procedures, without impeding a Party's ability to apply appropriate standards of quality, safety, and efficacy; and

(d) the need to recognize the value of innovative pharmaceuticals through the operation of competitive markets or by adopting or maintaining procedures that appropriately value the objectively demonstrated therapeutic significance of a pharmaceutical.

2. Transparency[2-C-1]

To the extent that a Party's federal healthcare authorities operate or maintain procedures for listing new pharmaceuticals or indications for reimbursement purposes, or for setting the amount of reimbursement for pharmaceuticals, under its federal healthcare programs, it shall:

(a) ensure that consideration of all formal proposals for listing are completed within a specified time;

[2-C-1] Pharmaceutical formulary development and management shall be considered to be an aspect of government procurement of pharmaceutical products for federal healthcare agencies that engage in government procurement. Government procurement of pharmaceutical products shall be governed by Chapter 15 (Government Procurement) and not the provisions of this Annex.

(b) disclose procedural rules, methodologies, principles, and guidelines used to assess a proposal;

(c) afford applicants timely opportunities to provide comments at relevant points in the process;

(d) provide applicants with detailed written information regarding the basis for recommendations or determinations regarding the listing of new pharmaceuticals or for setting the amount of reimbursement by federal healthcare authorities;

(e) provide written information to the public regarding its recommendations or determinations, while protecting information considered to be confidential under the Party's law; and

(f) make available an independent review process that may be invoked at the request of an applicant directly affected by a recommendation or determination.

3. Medicines Working Group

(a) The Parties hereby establish a Medicines Working Group.

(b) The objective of the Working Group shall be to promote discussion and mutual understanding of issues relating to this Annex (except those issues covered in paragraph 4), including the importance of pharmaceutical research and development to continued improvement of healthcare outcomes.[2-C-2]

(c) The Working Group shall comprise officials of federal government agencies responsible for federal healthcare programs and other appropriate federal government officials.

4. Regulatory Cooperation

The Parties shall seek to advance the existing dialogue between the Australian Therapeutic Goods Administration and the U.S. Food and Drug Administration with a view to making innovative medical products more quickly available to their nationals.

5. Dissemination of Information

[2-C-2] Nothing in this paragraph shall be construed as requiring a Party to review or change decisions regarding specific applications.

Each Party shall permit a pharmaceutical manufacturer to disseminate to health professionals and consumers through the manufacturer's Internet site registered in the territory of the Party, and on other Internet sites registered in the territory of the Party linked to that site, truthful and not misleading information regarding its pharmaceuticals that are approved for sale in the Party's territory as is permitted to be disseminated under the Party's laws, regulations, and procedures, provided that the information includes a balance of risks and benefits and encompasses all indications for which the Party's competent regulatory authorities have approved the marketing of the pharmaceuticals.

6. Definitions

For the purposes of this Annex:

federal healthcare program means a health care program in which the Party's federal health authorities make the decisions regarding matters to which this Annex applies.

Exchange of Letters on the PBS

[letter from Australia to the United States]

The Honourable Robert B. Zoellick
United States Trade Representative
600 17th Street, NW
Washington, DC 20508

Dear Ambassador Zoellick:

In connection with the signing on this date of the Australia-United States Free Trade Agreement (the "Agreement"), I have the honour to confirm the following understanding reached by the Governments of Australia and the United States in the course of negotiations regarding Annex 2-C (Pharmaceuticals):

1. In order to enhance transparency, meaningful consultation, and accountability in the process of selecting, listing, and pricing of pharmaceuticals under its Pharmaceutical Benefits Scheme (PBS), Australia shall provide an applicant seeking to have a pharmaceutical listed on the PBS formulary:

   (a) an opportunity to consult relevant officials prior to submission of an application for listing, including on the selection of a comparator pharmaceutical;

   (b) an opportunity to respond fully to reports or evaluations relating to the applications that are prepared for the technical subcommittees of the Pharmaceutical Benefits Advisory Committee (PBAC);

   (c) an opportunity for a hearing before PBAC while it is considering reports or advice from the technical subcommittees to the PBAC regarding applications; and

   (d) sufficient information on the reasons for PBAC's determination on an application, on an expeditious basis, to facilitate any application to the Pharmaceutical Benefits Pricing Authority.

2. Australia shall provide an opportunity for independent review of PBAC determinations, where an application has not resulted in a PBAC recommendation to list.

3 In order to make its process of selection, listing, and pricing of pharmaceuticals and indications under its PBS more expeditious, Australia shall:

(a) reduce the time required to implement recommendations of the PBAC, where possible;

(b) introduce procedures for more frequent revisions and dissemination of the Schedule of Pharmaceutical Benefits, where possible; and

(c) make available expedited procedures for processing of applications not requiring an economic evaluation.

4. Australia shall provide opportunities to apply for an adjustment to the price of a pharmaceutical under the PBS.

I have the honour to propose that this letter and your letter confirming that your Government shares this understanding in reply constitute an agreement between our two Governments, to enter into force on the date that the Australia-United States Free Trade Agreement enters into force.

I have the honour to propose that this understanding also be treated as an integral part of the Free Trade Agreement.

Sincerely,

MARK VAILE

The Honorable Mark Vaile MP

Minister for Trade

Parliament House

Canberra ACT 2600

Dear Minister Vaile:

I have the honor to acknowledge receipt of your letter of this date, which reads as follows:

"In connection with the signing on this date of the Australia-United States Free Trade Agreement (the "Agreement"), I have the honour to confirm the following understanding reached by the Governments of Australia and the United States in the course of negotiations regarding Annex 2-C (Pharmaceuticals):

1. In order to enhance transparency, meaningful consultation, and accountability in the process of selecting, listing, and pricing of pharmaceuticals under its Pharmaceutical Benefits Scheme (PBS), Australia shall provide an applicant seeking to have a pharmaceutical listed on the PBS formulary:

   (a) an opportunity to consult relevant officials prior to submission of an application for listing, including on the selection of a comparator pharmaceutical;

   (b) an opportunity to respond fully to reports or evaluations relating to the applications that are prepared for the technical subcommittees of the Pharmaceutical Benefits Advisory Committee (PBAC);

   (c) an opportunity for a hearing before PBAC while it is considering reports or advice from the technical subcommittees to the PBAC regarding applications; and

   (d) sufficient information on the reasons for PBAC's determination on an application, on an expeditious basis, to facilitate any application to the Pharmaceutical Benefits Pricing Authority.

2. Australia shall provide an opportunity for independent review of PBAC determinations, where an application has not resulted in a PBAC recommendation to list.

3. In order to make its process of selection, listing, and pricing of pharmaceuticals and indications under its PBS more expeditious, Australia shall:

   (a) reduce the time required to implement recommendations of the PBAC, where possible;

   (b) introduce procedures for more frequent revisions and dissemination of the Schedule of Pharmaceutical Benefits, where possible; and

   (c) make available expedited procedures for processing of applications not requiring an economic evaluation.

4. Australia shall provide opportunities to apply for an adjustment to the price of a pharmaceutical under the PBS.

I have the honour to propose that this letter and your letter confirming that your Government shares this understanding in reply constitute an agreement between our two Governments, to enter into force on the date that the Agreement enters into force.

I have the honour to propose that this understanding also be treated as an integral part of the Agreement."

I have the further honor to confirm that my Government shares this understanding and that these letters constitute an agreement between our two Governments, to enter into force on the date that the United States-Australia Free Trade Agreement (the "Agreement") enters into force and that this understanding is an integral part of the Agreement.

Sincerely,

ROBERT B. ZOELLICK