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AUSFTA
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Julia Thoener
The Acting Secretary
Joint Standing Committee on Treaties
Parliament House
Canberra ACT 2600
Email: jsct@aph.gov.au

Dear Ms Thoener

Australia – United States of America Free Trade Agreement

Thank you for the opportunity to make a submission on the above agreement. I have attached a copy of our comments and I would be pleased to discuss these with the Committee at any time.

Please contact Victoria Gilmore in the Canberra office (or professional@anf.org.au) if you require any other information.

Yours sincerely

JILL ILIFFE
Federal Secretary



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Submission on the Australia - United States of America Free Trade Agreement

Annex 2-C

Pharmaceuticals

The ANF is opposed to the inclusion of this Annex in the Free Trade Agreement. The pricing and listing arrangements of pharmaceuticals under the Pharmaceutical Benefits Scheme assists in the longstanding and bipartisan goal of providing Australians with high quality and affordable medicines. Trade agreements cannot take precedence over public health policies and this may be an outcome of the inclusion of this Annex in the Agreement. The ANF is very concerned that the Agreement will diminish the critical Australian principle of equitable access to medicines.

The current arrangements of listing pharmaceuticals on the PBS on advice to the Minister by the PBAC remains a cost effective mechanism which ensures that all pharmaceutical companies are treated equally and Australian consumers receive quality pharmaceuticals.

It is the view of the Australian Nursing Federation that the considerations of the PBAC and the consequent listing or otherwise in the PBS is not a restriction on trade and therefore should not form part of a free trade agreement.

The ANF considers that the proposed FTA in regard to the PBS is unbalanced and almost exclusively focuses on the rights of manufacturers at a potential cost to consumers.

Article 2 (f)

The ANF does not support the inclusion of a review mechanism for items not accepted for listing on the PBS. This is an additional step in the process for medicines to be listed on the Pharmaceutical Benefits Scheme in Australia and raises the possibility that undue influence may be exerted on the Pharmaceutical Benefits Advisory Committee as a result.

We are aware that the current limitations on the PBAC to publish information critical to their decision making arise from the commercial in confidence requirements of applicants. The ANF is concerned that this new step will lead to greater opportunities for the pharmaceutical manufacturers to utilise an army of publicists, lawyers and lobbyists to change the outcomes of a robust and respected system that is the PBAC.

Article 3

The ANF requests more information about the establishment of a Medicines Working Group. There is limited information about the issues referred to this Group and we are concerned that it will be used to make changes to the PBS including the way that medicines are listed on the PBS and the way that prices are negotiated for listing and following listing.

Article 5 The FTA contains provisions facilitating information about pharmaceuticals. The ANF opposes the advertising of pharmaceuticals to consumers. Research in the USA has found that advertising pharmaceuticals to consumers has encouraged consumption and consequently increased health costs.

Article 10.1 Cross border trade in services

Public services in Australia such as health are provided side-by-side and in competition with private service providers and in some instances the public provider may have a commercial aspect to their business. This may result in their inclusion rather than exclusion from the terms of this Agreement.

Article 10.4 Australia's public services such as health could, as a result of this Agreement, be opened up to health service providers from the United States of America with no requirements to either work as joint ventures or adhere to local regulations. While the reverse is true for the American market, it is very unlikely that Australian companies would have a major impact on the American health care industry which is already predominantly a private system.

Article 10.7 The nursing profession is included in this Chapter as a regulated profession. The ANF has sought clarification about the implications of this Chapter on the nursing profession but a response has not been received as yet. It appears that any proposed changes to nursing legislation in the Australian States and Territories will require advance notice being given to the United States. In addition it appears that Australia will receive advance notice of any planned changes to nursing legislation in any of the American States. If this is the case then will a general notification to a peak regulatory body be sufficient ie the Australian Nursing Council? It appears that either Party can challenge any changes to legislation which may be in the interests of the public's health and safety but add burden to the processes.

Annex 10-A
Article 4 The ANF position in relation to the granting of temporary licenses is that all licensed nurses must demonstrate that they meet the minimum professional standards ie Australian Nursing Council's core competency standards for nurses. Any diminution of this approach for the purposes of granting temporary licenses could directly and adversely impact on the health and safety of the Australian public. Granting of temporary licenses could also impact on the credibility of the nursing profession and should be opposed.

Articles 5 - 9 The membership of the proposed Professional Services Working Group requires clarification as a range of professions will be affected by this Chapter.

The ANF is not opposed to mutual recognition but we are concerned that the full costs of establishing, maintaining and monitoring this system with a country such as the United States of America will be borne by nurses and this is not acceptable. Financial assistance from the Governments is needed in order to advance this agenda as required under the Agreement.

Chapter 17

Intellectual property

Article 17.4

Extension of the terms of copyright will affect the Australian public in many ways including increased costs for education providers, libraries and public broadcasters. The Australian Government must be prepared to assist with meeting the costs of this Article as they have introduced this extension without receiving a mandate from the Australian public.

Article 17.9

The ANF understands that there may be some implications for generic manufacturers of pharmaceuticals in this Article. Of particular concern are the following possible outcomes:

- the lengthening of the life of a patent;
- the blocking, by legal means, of the development of a generic product by utilisation of completed trial results submitted to regulators by the brand name producers;
- linking marketing approval to patent status; and
- the extensions of data exclusivity.

The implementation of the above will result in:

- delayed introduction of generic products onto the market;
- prohibitive costs of producing generic products with their possible disappearance from the market altogether;
- reduction in the PBS' ability to price reference with other already genericised products; and
- an overall significant increase in costs to the Australian community.

It is recommended that wide consultation takes place prior to implementation to ensure that an outcome of the Agreement does not undermine the PBS pricing system and thereby threaten the affordability and sustainability of the entire scheme.

Chapter 18

Labour

The ANF position is that this chapter is a token reference to workers in both Australia and the United States of America. The agreement fails to prevent the governments from weakening their labour laws or indeed raising standards to meet ILO conventions. Australia's laws contain a number of restrictions on workers' rights that have been criticized by the ILO and other international Labour bodies such as the International Confederation of Free Trade Unions. For example, Australian workers do not at this time have the right to bargain collectively or to take industrial action. Submissions to the International Labour Organisation have been made as a result of these breaches of standards and the complaints have been upheld. The Agreement will, in fact, do very little to actually ensure that core workers' rights are respected and improved