CATHOLIC HEALTH AUSTRALIA

Submission to the Senate Select Committee on the Free Trade Agreement between Australia and the United States of America

April 2004

30 April 2004

Secretary
Senate Select Committee on the Free Trade Agreement
between Australia and the United States of America
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Dear Secretary

Please find attached Catholic Health Australia's submission to the Senate Select Committee Inquiry on the Free Trade Agreement between Australia and the United States of America.

Inquiries about this submission are welcome and may be directed to:

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Yours sincerely

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Introduction

Catholic Health Australia is the country's single largest ownership grouping of non government health, aged and community care services. Catholic Health Australia and its members are acutely aware of the value of and the effective contribution that the Pharmaceutical Benefits Scheme (PBS) makes to improving the health and wellbeing of all Australians and its role as a major pillar in Australia's health system. It is from this perspective that the following comments about the Australia-US Free Trade Agreement and the implications for Australia and our PBS are made.

Further information about Catholic Health Australia is provided at the end of this submission.

Specific comments on the Australia-US Free Trade agreement

Annex 2-C - Pharmaceuticals

AGREED PRINCIPLES

The Annex lists the following Agreed 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 recognise 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.

While recognising that these principles are contained in a Trade Agreement and therefore the stated focus is more aligned to industry and trade-related principles, Catholic Health Australia considers that the principles as outlined are too heavily weighted towards the preferences and objectives of manufacturers with scant attention to the needs of consumers and the general health benefits which should be of paramount importance and reflected in such an Agreement. These principles should be expanded to include a reference to ensuring that all pharmaceuticals available in the Australian market are safe and of high quality and remain affordable and accessible to all Australians.

TRANSPARENCY

Under the heading of Transparency, the Free Trade Agreement (Annex 2-C, Pharmaceuticals) states:

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

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

(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.

Catholic Health Australia supports measures which will improve and build-on the existing transparency and accountability measures in the Pharmaceutical Benefits Scheme. It is in the interests of the public, health professionals, the Government and the pharmaceutical companies to be clear about the processes that are used to assess and approve a pharmaceutical for use in Australia. It is also important to set clear timeframes as part of this accountability process together with parameters for the information that should be provided in writing to applicant companies and the public about the outcomes of an approval process whether it was successful or not.

On face value it would also appear reasonable to enable applicants the opportunity to provide comments on their application at appropriate points in their application process. However, Catholic Health Australia is concerned about how this provision may work in practice. One of the strengths of the current application process is the perceived and real independence of the Pharmaceutical Benefits Advisory Committee (PBAC). It is not clear from the documentation in the Free Trade

Agreement what processes will be invoked to enable applicants to comment throughout the process and what pressure they will be able to exert.

Recognising the influence of major pharmaceutical companies, Catholic Health Australia believes there are real grounds to question the pressure that such companies with well-resourced lobbying and public relations departments will be able to place on the PBAC members during the application process.

In a similar vein, the Free Trade Agreement lacks any substantial detail as to how the independent review process that may be invoked at the request of an applicant directly affected by a recommendation or determination will work. As such it is not possible to comprehensively comment on its merits or otherwise. Catholic Health Australia considers that companies are entitled to a comprehensive explanation for the reasons behind a decision or determination made by PBAC. The commentary from the Government since the release of the Free Trade Agreement suggests that this review mechanism will not be able to overturn a PBAC decision. This begs the question as to what the purpose of this review mechanism will actually be and who will it report to? Following on from this, what will be the required steps and action when an independent review is received? This is important information which makes it very difficult to assess the true merits of this proposal.

There have been legitimate concerns raised by other bodies and in the press which Catholic Health Australia shares as to the legal and bureaucratic processes that large pharmaceutical companies will use within the parameters of this vague reference. There is no point being naïve about this – large pharmaceutical companies are well resourced with legal and public relations expertise. If there is scope to question and dispute a legitimate independent decision that goes against them, they will use every means possible to do so and a decision delayed by reviews will affect Australians' access to pharmaceuticals.

The possibility of delay also arises as a result of some ambiguity and potential inconsistency between the espoused principles in the Free Trade Agreement to promote timely and affordable access to innovative pharmaceuticals through transparent, expeditious and accountable procedures (Annex 2-C – 1(c)), while at the same time the transparency measures are introducing new procedures to enable pharmaceutical companies to be more actively involved in the assessment and approval process. These proposed new measures enable pharmaceutical manufacturers to be more involved both during the assessment process and afterwards should they choose to have a decision reviewed by the independent review process. It is unclear as to how these provisions can support more timely and expeditious approval processes.

MEDICINES WORKING GROUP AND REGULATORY COOPERATION

Catholic Health Australia has no in-principle objections to the establishment of the Medicines Working Group (Annex 2-C, para 3) and the increased regulatory cooperation between the Australian Therapeutic Goods Administration (TGA) and the U.S. Food and Drug Administration (Annex 2-C, para 4). Beyond this, in terms of the Medicines Working Group, there is not enough detail to comment on its merits and objectives, and there is some ambiguity about what influence this Group will have in the overall pharmaceutical approval process. Catholic Health Australia would have grave concerns if there was to be US bureaucratic influence on Australia's pharmaceutical approval process. Similarly, better communication and cooperation between our TGA and the US Food and Drug Administration is welcome, but not if the purpose of this regulatory cooperation is to enable greater American influence on the pharmaceuticals that are approved in Australia without the rigorous testing that Australia's current processes require.

DISSEMINATION OF INFORMATION:

The clause on Dissemination of Information (Annex 2-C – para 5) is also potentially a double-edged sword. Consumers are entitled to be able to research the benefits and potential side-effects of particular medication. Enabling manufacturers to place this information on appropriate websites is an obvious mechanism for this information to be easily accessible. Catholic Health Australia's reservation with this clause relates to the limits that will be placed on manufacturers regarding what is considered "truthful information" and what is considered advertising. The Federal Government has recently spent millions of dollars on raising awareness about the importance of the PBS and its value together with educating the public about why is important to use medications wisely and not wastefully. It would be a tragic outcome if this awareness raising effort was overtaken with excessive and unnecessary use of medications because of sophisticated marketing and advertising techniques of pharmaceutical companies. Without more detailed procedures and principles, it is difficult to see how this risk might be mitigated.

INTELLECTUAL PROPERTY AND PATENT LAWS (article 17):

Catholic Health Australia is concerned that the requirements under the Free Trade Agreement which toughen intellectual property and patent extensions may have negative consequences for the cost and availability of generic medications in Australia. Any rules which delay the availability of generic medicines which are cost-effective has the potential to keep prices of medications high and subsequently increase costs to the PBS and consumers for over-the-counter medications. Catholic Health Australia would like to see further assurances that the intellectual property and patent provisions will not be an inhibitor for manufacturers to produce generic medications and that these provisions will not increase the cost of medications in Australia.

BLOOD PLASMA PRODUCTS

One final concern that Catholic Health Australia notes in the Free Trade Agreement is the reference made to the treatment to be accorded products derived from blood plasma and blood fractionation services for the production of such products (Exchange of Letters on Blood Plasma Products between Mark Vaile and Robert Zoellick). The references in these letters imply strong impositions on how Australia will regulate its blood products and services. It sets clear directions for the policies of future Australian governments "Australia shall undertake a review of its arrangements for the supply of blood fractionation services that will be concluded by not later than 1 January 2007. The Commonwealth Government will recommend to Australia's States and Territories that the future arrangement for the supply of such services be done through tender processes consistent with Chapter 15 (Government Procurement)" [Para 2 in the exchange of letters].

Catholic Health Australia's concern with this reference is that the Free Trade Agreement is setting policy directions for all Australian Governments without adequate reference to the particular public health policy imperatives that Australia should have in such an important area. This concern is exacerbated by the references made in paragraph 4 in the Exchange of Letters which states "A Party may require that any producer of blood plasma products or supplier of blood fractionation services fulfil requirements necessary for ensuring the safety, quality and efficacy of such products. Such requirements shall not be prepared, adopted, or applied with a view to or with the effect of creating unnecessary obstacles to trade." It appears from this statement that the safety, quality and public health imperatives from Australia's perspective have been watered down because they are not given any greater importance than accommodating free trade. This may not be in Australia's best interest.

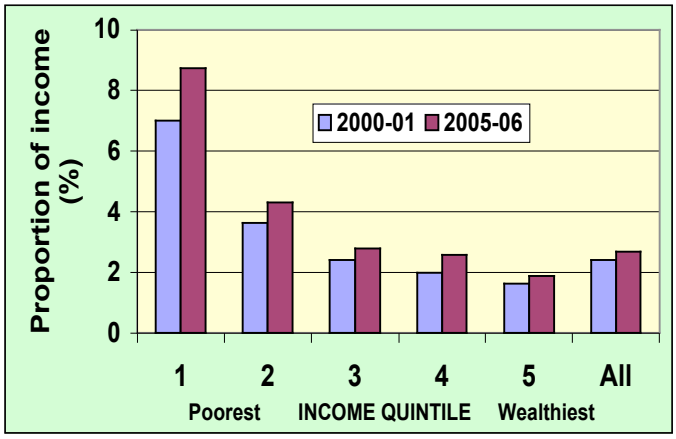
GENERAL COMMENTS ON THE PBS AND KEEPING COSTS LOW FOR CONSUMERS – PARTICULARLY THOSE ON LOW INCOMES

By international comparisons, Australia is a relatively modest spender on pharmaceuticals due in no small part to the existing cost effectiveness processes in place for PBS listing.

In 2000-01, the highest income groups spent less than 2% of their incomes on pharmaceuticals while for low income groups who sit just outside the thresholds for concessional PBS access, pharmaceuticals claimed 7% of family income, which may increase to nearly 9% by 2005-06 as illustrated in Chart [1].[1]

[1] Source, including Chart 5, from "Projecting pharmaceutical expenditure by patients and government" *NATSEM News*, Issue 18, February 2002.

Chart 1: Proportion of family income spent on PBS-subsidised drugs by general patients (NATSEM)



A study in 2002 found that almost 20% of Australians reported not filling a prescription in the previous year due to the copayment cost, yet these people are the ones who need it most as socio-economic status increases the risk of poor health in old age.[2]

Similarly in research into the impact of government fees and charges on people with low incomes, the disproportionate effect of increased PBS copayments, on low income families was reported.[3] In addition, the cost of over the counter medications not listed on the PBS caused considerable hardship for those on low incomes trying to prioritise health care ahead of telephone, electricity, food and school excursions. The effect was particularly hard felt by those with chronic illnesses and those requiring multiple medications.

This research demonstrates just how valuable our PBS is to all Australians, but particularly those on low incomes and those with chronic health conditions. While recognising that there are strategic reasons that the Australian Government has agreed to entering into a Free Trade Agreement with the United States, all measures must be taken to ensure that any amendments and changes resulting from the Free Trade Agreement that affect access and cost of pharmaceuticals in Australia do not lead to a preference for industry needs over the health and wellbeing of Australians. The sustainability of the PBS is paramount and any changes which lead to a general rise in the cost of medications will only serve to jeopardise the future of the PBS and the health of Australians.

[2] Kinnear, P "Ageing: will the real culprit please stand up?" *Australian Policy Online*, 31 May 2002.
[3] Helen Smallwood, Marilyn Webster, Valerie Ayers-Wearne, *User Pays. Who Pays?,* Good Shepherd Youth and Family Service, 2002, pp. 60-72, 90, 96.

The Catholic Health, Community and Aged Care Sector – Background

CHA is the largest non-government provider grouping of health, community and aged care services in Australia, nationally representing Catholic health care sponsors, systems, facilities, and related organisations and services.

The sector comprises providers of the highest quality care in a network of services ranging from acute care to community based services. These services have been developed throughout the course of Australia's development in response to community needs. The service providers carry on centuries-old traditions of bringing Christ's healing ministry to those who suffer – the ill, the disabled, the elderly, the disadvantaged, the marginalised, the poor, serving those that others with a profit motive do not. The services return the benefits derived from their businesses to their services and to the community; they do not operate for profit; they are church and charitable organisations.

The sector plays a significant role in Australia's overall health care industry, representing around 13% of the market and employing around 30,000 people.

The Catholic health ministry is broad, encompassing many aspects of human services. Services cover aged care, disability services, family services, paediatric, children and youth services, mental health services, palliative care, alcohol and drug services, veterans health, primary care, acute care, non acute care, step down transitional, rehabilitation, diagnostics, preventive public health, medical and bioethics research institutes.

The Sector Snapshot

17000 residential aged care beds
5334 independent living and retirement units
4417 community aged care packages
4729 home and community care services
59 hospitals
8000 hospital beds
39 privately funded hospitals
20 publicly funded hospitals
7 teaching hospitals
17 rural and regional hospitals
157 rural and regional aged care services
publicly and privately funded collocated facilities,
across six states and one territory

Foundational Principles

The Catholic health, community and aged care ministry is defined by these interrelated foundational principles:

Dignity: Each person has an intrinsic value and inalienable right to life. Everyone has a right to essential comprehensive health care.

Respect for Human Life: From the moment of conception to natural death, each person has inherent dignity and a right to life consistent with that dignity.

Human Equality: Equality of all persons comes from their essential dignity. While differences are part of God's plan, social and cultural discrimination in fundamental rights are not part of God's design.

Service: Health care is a social good. It is a service, not a commodity used for maximising profit.

Common Good: Social conditions should allow people to reach their full human potential and to realise their human dignity. Equitable access to care, developing research and training, and conducting professional inquiry into the social, ethical and cultural aspects of health, builds social conditions and communities that respect human life and allow people to realise their potential.

Association: Every person is both sacred and special. How we organise society – in economics, politics, law and policy – directly affects human dignity and the capacity of individuals to grow in community.

Preference for the Poor: Priority must be given to the needs and opportunities of the poor and disadvantaged. This encompasses economic, cultural and individual notions of poverty and disadvantage.

Stewardship: Health resources should be prudently developed, maintained and shared in the interests of the community as a whole and balanced with resources needed for essential human services.

Subsidiarity: The identified needs of individuals and the community are best addressed at the level where responses and resources are available, appropriate and effective.