April 13, 2004
Committee Secretary
Joint Standing Committee on Treaties
Department of House of Representatives
Parliament House
CANBERRA ACT 2600

Dear Madam / Sir,

I have particular concerns about the impact of the AUSTUS-FTA on our Pharmaceutical Benefits Scheme (PBS).

The following submission is based at talks I have given on this subject at public meetings held in both Melbourne and Sydney.

Please note that this material has been prepared in my capacity as a concerned Australian citizen; it does not necessarily represent the views of any organisation with which I am affiliated.

Sincerely,

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The FTA & the PBS: Public Health & Consumer Concerns

Dr. Ken Harvey
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Talk outline

CAMPAIGN FOR ACCESS TO ESSENTIAL MEDICINES

- Remind you how and why the PBS emerged as an FTA issue.
- Comment on FTA clauses that give rise to concern.
- Draw some conclusions.

The PBS emerges as an FTA issue

- In January 2003, the Pharmaceutical Research Manufacturers of America (PhRMA) lobbied US trade negotiators to seek Australian government commitment to, "refrain from trade distorting, abusive, or discriminatory price controls such as current PBS reference pricing" (Burton 2003).
- In October 2003, President George Bush told Prime Minister John Howard that raising drug prices is a key goal for United States negotiators in any FTA deal. Mr Bush said his pharmaceutical industry believes **some countries do not pay their share of the cost of research and development to create new medicines, making US consumers pay the bill** (Colebatch 2003).

Why did the PBS get into the FTA?

Conflicting goals:

PBS:

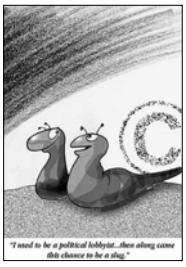
- Equity of access to necessary drugs for all Australians at an affordable price by:
  - Pharmacoeconomic analysis (pay what it's worth)
  - Monopsony buying power (counters monopoly power of pharmaceutical companies during patent protection)
  - Reference pricing (subsidise only the lowest price product in a generic group and in some therapeutic classes)
  - Generic substitution

Big PHARMA:

- Profitability for shareholders by:
  - R&D to create innovative drugs that meet real &/or perceived health needs
  - Pricing drugs to maximise return on investment
  - Protecting and extending patent life ("ever-greening")
  - Promoting increased drug use
  - Influencing medicinal drug policy to create more favourable market conditions

Influencing drug policy

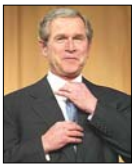
PhRMA — *Expenditure Millions 2003–2004*



- Pharmaceutical lobbying at the US Federal level: US $73 m. (There are 625 pharmaceutical lobbyists on Capitol Hill; more than the number of Congressman),
- Lobbying at US State level: US $49 m.
- **Fighting price controls and protecting patent rights in foreign countries and trade negotiations: US $18 m.**
- Fighting 'a union-driven initiative in Ohio' which would lower drug prices for people who have no insurance to cover such costs: US $16 m.
- Lobbying the US Food and Drug Administration: US $5 m. (Pear 2003)

Influencing drug policy

PhRMA
Expenditure Millions
2003–2004



- Payments to research and policy organisations, 'to generate a higher volume of messages from credible sources' sympathetic to the pharmaceutical industry: US $2 m.
- Funding a standing network of economists to speak against US drug price controls: US $1 m.
- Changing the Canadian Health Care System: US $1 m.

(Pear 2003)

- During the last Presidential election, the American pharmaceutical industry contributed $14 million to George Bush's campaign.

Where does PhRMA money go?

- Over the last ten years, the pharmaceutical industry has been by far the most profitable in the US.
- The pharmaceutical giants spend 2-3 times more on marketing and administration as on R&D; their profits are about twice R&D costs.
- For example, last year GlaxoSmithKline spent 37 percent of its revenues on marketing and administration, 14 percent on R&D, while making a 28 percent profit.

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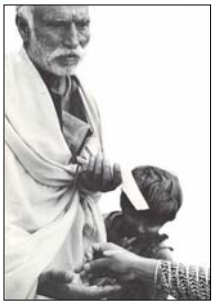
Where does PhRMA money go?



CEO (2002-2003) remuneration:

- **Genentech: US $63 m.**
- **Pfizer: US $ 50 m.**
- **Schering-Plough: US $ 46 m.**
- **Amgen: US $ 44 m.**
- **Abbott: US $ 28 m.**
- **Lilly: US $23 m.**

Business Week 2003, April 21, pg 92.

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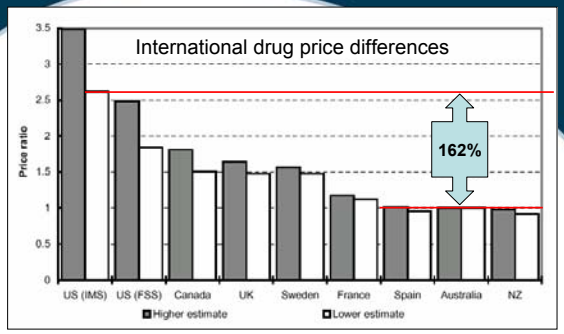
Why doesn't PhRMA like the PBS?



Productivity Commission Research Report, July 2001 (top 150 PBS drugs)

Does Australia pay its way in drug R&D?

- While drug prices in Australia are from 5% to 45% lower than those in similar countries price differences vary across different categories of pharmaceuticals:
  - prices for new innovative drugs are much closer to those in the other countries
  - largest price differences for 'me-too' pharmaceuticals (modified versions of older drugs similar in clinical value to drugs already available) and generics.
- In addition, the Australian Department of Industry, Tourism & Resources administers a $300 million Pharmaceutical Industry Investment Program (PIIP) that provides additional rewards for pharmaceutical manufacturers for undertaking research and development in Australia. (P3 from July 2004).

US drug prices (and profits) are too high!

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Given that background

It's not surprising that the FTA became a PBS negotiating battleground. The question is, "Who won?"

- Mark Vaile said, "The PBS, in particular the price and listing arrangements that ensure Australians access to quality, affordable medicines, remains intact' (Vaile 2004).
- US Senator Jon Kyl said, " a breakthrough made with respect to pharmaceuticals". (Kyl 2004).
- *Medicines Australia* said, "The triumph is in the text" (Haynes 2004).

FTA: Public health and consumer concerns

Relevant sections of the agreement are (DFAT 2004):

- Pharmaceuticals (Annex 2C)
  - Principles
  - Transparency
  - Medicines Working Group
  - Dissemination of information

- Intellectual Property Rights (Chapter 17).

Annex 2C: Principles

Unbalanced

- The Parties are committed to facilitating **high quality health care and continued improvements in public health** for their nationals. In pursuing this objective, the Parties are committed to the following principles:
  - **the important role played by innovative pharmaceutical products** in delivering high quality health care;
  - **the importance of research and development** in the pharmaceutical industry and of appropriate government support including through **intellectual property protection** and other policies;
  - 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
  - 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.

Unbalanced principles

- Focus entirely on the rights of manufacturers of innovative pharmaceutical products
- Does not mention the rights of consumers to equitable access to affordable drugs.
- Leaves out the hard won principle of the Doha Declaration on the Trade Related Intellectual Property Rights (TRIPS) Agreement in Public Health:
  - Trade agreements should be interpreted and implemented to protect public health and promote universal access to medicines (Correa 2002).
- Ignores the crucial role of generic manufacturers in protecting public health (by moderating prices when patents have expired or in health emergencies).

Annex 2C: Transparency

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

NEW

Independent review

- In briefings, DoHA has drawn a distinction between the review mechanism proposed in the FTA and a comprehensive appeals process:
  - DoHA argues that the proposed review process will not be able to overturn a PBAC decision.
  - **This interpretation is unsupportable.**
  - If reviews cannot result in PBAC decisions being overturned then what is the point of them?
  - Why else would *Medicines Australia* say, "The triumph is in the text" and applaud the introduction of an "appeals mechanism" (Haynes 2004).
  - It seems inevitable that reviews of negative PBAC decisions will allow the numerous lawyers, large budgets, and formidable public relations machines of US pharmaceutical companies to wear PBAC down.
  - The end result is likely to be drugs listed at higher prices than the PBAC originally thought justified by the pharmacoeconomic evidence.

Annex 2C: Medicines Working Group

N.B. Focus

- The Parties hereby establish a **Medicines Working Group**.
- 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.
- The Working Group shall comprise officials from federal government agencies responsible for federal healthcare programs and other appropriate federal government officials.

Medicines Working Group

- Ironically, the public health goal of equitable access to affordable drugs is not on the agenda (if it was the US could have much to learn from Australia).
- DoHA argues that the working group is similar to others set up for other industries affected by the FTA; that the group isn't a policy-making body and will only serve as a discussion forum.
- **Once again, US officials appear to have a different view of the likely impact of working group than do Australian officials.**
  - **US Senator Jon Kyl, "..I know there is much more work that needs to be done in further discussions with the Australians"**

Annex 2C: Information dissemination

DTCA?

- Each Party shall permit a pharmaceutical manufacturer to **disseminate to health professionals and consumers via the manufacturer's Internet site registered in the territory of a Party, and on other Internet sites registered in the territory of a 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 under each 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.

Information dissemination

- DoHA is adamant that these provision about the Internet contain nothing new, and merely reiterates existing law in both countries.
- Others worry that this clause could allow 'direct to consumer' advertising (DTCA) in Australia. DTCA is legal in the United States but illegal here; it substantially increases the use of advertised products, encouraging overuse and higher health care costs (Mintzes et al. 2002).
- **If this provision contains nothing new why is it the FTA?**

17. Intellectual Property Rights

Delayed entry of generic drugs?

- 9.3 **Patent Extensi**
  - Consistent with A… requires that an ex… compensate an ov… process
- 9.4 **Marketing of a Gene… of a patented medicine to be prevented during … Term (Article 17.10.5(a))**
  - The Agreement requi… Australia provide measures in the marketing approval process to … a person from entering the market with a generic version of a patent… medicine before a patent covering that product has expired. **It will … necessary to make some legislative change to provide for this.**
- 9.5 **Notification of Intention to Market during the Patent Term (Article 17.10.5(b))**
  - The Agreement requires that a patent owner be notified of an application for marketing approval in the limited cases in which the person seeking the approval considers the patent invalid and intends to market a generic version of a patented product before the patent expires. **This will require legislative change.**

Intellectual Property Rights

Article: 17.10.5

- A recent Canberra DoHA / DFAT briefing confirmed that the Therapeutic Goods Act will need to be changed as a result of the IP provisions of the FTA
- Negotiators insisted that any changes would only affect 6% - 7% of generic applications.
- Phillip Davies, DoHA Deputy Secretary, said, 'we believe that ... we can implement the changes to ensure that the likelihood of the delaying the entry of generic medicines to the market is very small'.
- **This opinion is not exactly encouraging.**

FTA-PBS: Summary

US Trade Representative Zoellick & Australian Trade Minister Vaile

- Australian negotiators believe they have, "held the line" on the PBS.
- The Americans disagree!
- **They can't both be right!**
- Clearly the FTA opens up additional pressure points on the PBS that are likely to ultimately result in higher drug prices, less generic competition and more pharmaceutical promotion.

More importantly:

- THE FTA-PBS negotiations highlight the fact that health (and access to pharmaceuticals) is a **contested territory** between those who believe it is:
  - **An individual responsibility best left to market forces (U.S. P*h*RMA view)**
  - **A civic good for which the community accepts shared responsibility (PBS, WHO, MSF, Oxfam, etc).**

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Senate Select Committee on the FTA | Joint Standing Committee on Treaties

- **Support the National Medicare Alliance;**
- **Defend the PBS;**
- **Write submissions to the Senate FTA inquiries;**
- **Support international campaigns for equitable access to essential drugs;**
- **Make these issues election issues.**

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References

- Harvey K. *Pharmaceutical benefits and free trade: trouble ahead for subsidised medicines in Australia?* The Australian Review of Public Affairs Drawing Board Digest (March 19, 2004) . Available: http://www.econ.usyd.edu.au/drawingboard/digest/0403/harvey.html
- Other references available on request from:
  - k.harvey@latrobe.edu.au

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