Senate Inquiry into the AUST-US FTA:
Questions on Notice to Dr. Ken Harvey from Senator Ferris

Question 1

In your paper of March 19, 2004 entitled, *Pharmaceutical benefits and free trade: trouble ahead for subsidised medicines in Australia?*[1] you concluded that consumer and medical groups are right to be apprehensive about the future of the PBS under the AUST-US FTA. Do you still stand by what you said in that paper?

Answer

Yes! Subsequently a number of other academic experts, health and consumer organisations have reiterated my concerns.[2,3,4]

Question 2

Can you point to any part of the fine print of the FTA that justifies your rejection as "unsupportable" DoHA's assurance that the (FTA) review process for listing pharmaceuticals "will not be able to overturn a PBAC decision" when there is a statutory requirement for the Minister to take listing action only on the recommendation of the PBAC – and any review recommendation must therefore go back to the PBAC (paraphrased)?

Answer

Your outline of PBS listing procedure is correct but it ignores the new pressure that the FTA will apply to the PBAC by several provisions that relate to the PBS.

First, the principles outlined in Annex 2-C of the FTA[5] are unbalanced in that they focus entirely on the rights of pharmaceutical manufacturers and neglect the rights of consumers to equitable access to affordable drugs. The principles leave out the key principle of the Doha Declaration[6] on the TRIPS Agreement and Public Health, adopted by the WTO Ministerial Conference in November 2001, namely that trade agreements should be interpreted and implemented so as to protect public health and promote access to medicines for all (the latter is the fundamental rationale of the PBS).

Instead, the principles in Annex 2-C are heavily weighted towards the agenda of the US pharmaceutical industry, emphasizing "innovation," "research and development" and "competitive markets". Clearly, these "principles" will be brought to the table of the "review mechanism" by pharmaceutical manufacturers whose products receive a negative PBAC decision allowing them to argue for a listing at a higher price than the PBAC originally thought justified on the pharmacoeconomic evidence.

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1 http://www.econ.usyd.edu.au/drawingboard/digest/0403/harvey.html
2 Drahos P, Henry D. [Editorial] The free trade agreement between Australia and the United States: Undermines Australian public health and protects US interests in pharmaceuticals. BMJ 2004;328:1271-1272 (29 May), Available: http://bmj.bmjjournals.com/cgi/content/full/328/7451/1271?etoc
3 Faunce TA. FTA undermines principle of affordable drugs for all. Canberra Times, Tuesday, 25 May 2004
4 e.g. Senate FTA Inquiry; Submission 75, Generic Medicines Industry Association Pty Ltd.; Submission 407, Doctors Reform Society; Submission 369, Public Health Association of Australia Inc.; Submission 369, Australian Nursing Federation; Submission 405, Catholic Health Australia; Submission 445, National Centre for Epidemiology and Population Health; Submission 522, Australian Consumers' Association; All available at: http://www.aph.gov.au/Senate/committee/freetrade_ctte/submissions/sublist.htm
5 http://www.dfat.gov.au/trade/negotiations/us.html
6 http://www.who.int/medicines/organization/ood/trips_med.shtml

Second, under the FTA dispute resolution procedures of chapter 21, an unelected panel of three nominated trade lawyers (article 21.7) will have the power to interpret compliance with obligations in the FTA, including the required alterations to shift the focus of the PBS toward greater rewards for drug "innovation". For example, faced with determining whether the PBS "review mechanism" actually fulfils FTA obligations, the panel will rely upon the interpretive "principles" set out at the beginning of Annex 2-C.

As previously mentioned, these principles are heavily weighted towards the agenda of the US pharmaceutical industry. The principles contain no unqualified reference to universal access to affordable and essential medicines. In addition, article 21.2 (c) allows a damages claim where a "benefit" the US could reasonably have expected to accrue under the FTA is not realised even though no specific provision has been breached. The end result is that PBAC decisions not to list "innovative" new US drugs (because they were not cost-effective) will be made in the shadow of possible US trade retaliation in important areas such as manufacturing and agriculture.

This process will seriously compromise the negotiating position of the PBAC. At present, the committee commissions sophisticated economic evaluations of each new drug and decides whether the price requested by the company represents fair value in terms of the health benefits the drug is likely to provide. If the answer is no, companies must reduce their price or find new data to justify the price they want. Often, the price comes down.

If, rather than re-submitting their application to the PBAC, sponsor companies can now go to an alternative "review process" based on the principles of Annex 2-C and supported by the dispute resolution clauses of the FTA, then not only has PBAC lost a considerable amount of bargaining power but it its also likely that PBAC decisions could be overturned by the dispute resolution process.

In addition, once an item has been recommended for listing by PBAC (perhaps under the duress outlined above) the Health Minister has the power to change the listing criteria, for example by increasing the price as Minister Michael Wooldridge did with Celecoxib (Celebrex®).[7]

Question 3

Is your concern that a future government may change the present system? Couldn't a future government establish a review process without their being an FTA (paraphrased)?

Answer

I have no problems with a democratically elected Australian government establishing a balanced review process of PBAC decision-making (including decisions to list and not to list) as long as the review is focused on improving the PBS in accord with its underlying principle, namely the timely, efficient and equitable provision of necessary drugs at a price the Australian community can afford.

However, this FTA "review process" has resulted from pressure by American pharmaceutical

[7] Dowden, J. 2003, 'Coax, COX and cola' [Editorial], *Medical Journal of Australia*, vol. 179, pp. 397–398 [Online], Available: http://www.mja.com.au/public/issues/179_08_201003/dow10457_fm-2.html.

manufacturers,[8,9] not the Australian government and it is clearly aimed at undermining the PBS and increasing Australian drug prices, not establishing more equitable and efficient PBS processes.

Question 4

Are you aware of consumer concerns over the non-listing, or excessive delays in listing, by PBAC of various drugs (paraphrased)?

Answer

I am well aware of these concerns, some of which are genuine; a number of which are prompted by industry funded "patient groups" or industry sponsored "advertorials" &/or press releases.

There is an inevitable tension between:

- Consumers who ideally would like all possible treatment modalities available at no cost to themselves,
- Health professionals who wish to do everything possible for their patients regardless of the cost to the community,
- Pharmaceutical manufacturers who wish to gain the highest price possible for their products (to benefit their shareholders and assist the discovery of new drugs), and
- Governments who have the responsibility to purchase health care wisely, mindful of opportunity costs.

The answer to these dilemmas is a National Medicinal Drug Policy (NMDP) which attempts to balance these competing demands. In this respect, Australia is regarded as a world leader with our four pillared NMDP that assures:

- Quality of drug products (Therapeutic Goods Administration),
- Equity of access (PBS),
- Quality of use (Therapeutic Guidelines, AMH, NPS, etc.), and
- A viable, export orientated industry (Pharmaceutical Industry Investment Program).[10]

Inevitably, given the above tensions, there will be occasional delays (or failure) for new drugs to gain access to the PBS, usually because the manufacturer has asked for a price not justified by the benefit of the drug or, in the case of male erectile dysfunction medication, the PBAC approved the drugs (for limited indications) but the Health Minister (Kay Paterson) declined to list because of concern about a cost blow-out.

The answer to concerns about such processes is not a one-sided, US industry driven review of

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8 Pharmaceutical Research and Manufacturers of America. 2003, 'PhRMA "Special 301" submission to the Office of the United States Trade Representative: Australia', Pharmaceutical Research and Manufacturers of America. Available: http://www.cptech.org/ip/health/c/australia/phrma-au-2003.html
9 Colebatch T, Bush wants end to medicine subsidies, *The Age*, 24/10/2003; Pg 5.
10 Harvey K, Murray M. Medicinal drug policy, in The Politics of Health, 2nd Ed., Gardner H (Ed) Churchill Livingstone, Melbourne, 1995, 238-283.

negative PBAC decisions but an open and transparent process that includes making public PBAC submissions by industry (ironically still protected by "commercial-in-confidence" clauses in the "transparency" provisions of Annex 2-C).

Question 5

Are you aware of concerns of the medical profession (about delayed PBS listing)?

Answer

The answer is the same as 4 above, with the additional comment that although many physicians genuinely wish to try the latest (and most expensive drugs) in order to benefit their patients, few reflect that, given a finite health budget, spending large amounts of money for minor (or dubious) benefit on one patient may deny another patient treatment which has a proven and substantial benefit. In addition, some clinicians become paid spokespersons for certain pharmaceutical companies which can cause them to lose their objectivity (hence the need for declaration of interests). The purpose of the PBAC process is to objectively determine what drugs the country can afford.

Question 6

Why is price the only criteria on which you expect appeals to be based (paraphrased)?

Answer

In January 2003, the Pharmaceutical Research and Manufacturers of America (PhRMA) lobbied US negotiators for the FTA with Australia to seek a commitment from the Australian government to, "refrain from trade distorting, abusive, or discriminatory price controls such as the current PBS reference pricing".[6] In October 2003, President George Bush allegedly told Prime Minister John Howard that raising Australian prices for US pharmaceuticals was important to ensuring that consumers in all countries, not just the US, paid for high research and development (R&D) costs.[7] The Americans have been quite open that the purpose of including the PBS in the FTA negotiations was to achieve higher drug prices in Australia.

Question 7

Why do you say the review process will "wear down" PBAC when it is to be independent and not amenable to other than the same submissions as made to PBAC (paraphrased).

Answer

See the answer to question 2 above.

Question 8

Do you agree that, under the FTA, the review process can be whatever the Australian government chooses it to be, as long as it is in the spirit of the agreement (paraphrased)?

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Answer

The FTA is a bilateral agreement between the US and Australia. The spirit of the agreement that Australia has entered into is spelled out in the unbalanced principles of Annex 2-C and the consequences will be as outlined in my answer to question 2 above.

Question 9

Do you really believe that PBAC decisions have always been perfect and there is no merit in a review (paraphrased)?

Answer

All humans (and committees) are fallible. However, the PBAC has a good track record and its past decisions have stood the test of High Court challenges. Equally, I would not argue against a balanced and transparent review process that was instituted because of genuine and demonstrable need. However, what we have in the FTA is a review process instigated by US PhRMA with the expressed purpose of undermining the PBS and raising Australian drug prices!

Question 10

What is your view of review processes in general?

Answer

See answer to question 9 above.

Question 11

The Industry Commission in 1996 suggested that a review process might improve PBAC transparency and accountability. Do you agree (paraphrased)?

Answer

If the need was compelling in 1996 I find it ironic that it took 8 years and pressure from US PhRMA to move the government to action! See also answer to question 9 above. Transparency and accountability could be considerably improved if the industry allowed the PBAC to release its evaluations in full and if the industry all released their own submissions in full. Both are currently regarded as commercial-in-confidence by the industry.

Question 12

Would you support the FTA transparency & review processes if it brought about faster results and removed bureaucratic delays (paraphrased)?

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Answer

I support greater transparency and efficiency of PBAC & PBS processes. As I mentioned in my answer to question 11, if this was a compelling need why has the government done nothing since 1996? Why is this process linked to a FTA which contains many more worrying provisions than "greater transparency and efficiency"?

Question 13

Why the concern about industry impediments to transparency (paraphrased)?

Answer

Transparency of PBAC processes are currently reasonable; what is lacking is transparency of the data supplied by industry. I support the following resolution of the Federal Council of the AMA in this regard:

> FEDERAL COUNCIL OF AMA CALLS FOR CHANGES TO FTA ON PBS.
>
> On Friday 28 May 2004, the Federal Council of the AMA passed the following resolution. As a result it is now Federal AMA policy that certain conditions be imposed on the text of the Australia-United States Free trade Agreement (AUSFTA) before it be passed by the Australian Senate.
>
> "The AMA holds that the Australia-United States Free Trade Agreement (AUSFTA) be subject to the following conditions:
>
> 1. There is full and open transparency of both Pharmaceutical Benefits Advisory Committee (PBAC) decision-making processes and of submissions to the PBAC.
>
> [This condition requires an exchange of letters clarifying Annex 2C of the AUSFTA under the heading of "transparency." A reasonable example would be a clarification requiring an explicit statement that all documentation related to submissions by pharmaceutical manufacturers to the PBAC be made available to the public on the web].
>
> 2. etc.

Question 14

Why do you assert that the FTA will result in upward price movements to reward "innovative" pharmaceuticals (paraphrased)?

Answer

Because that is the thrust of the principles that the Australian government agreed to in Annex 2-C rather than the current PBS principle of paying what a drug is worth on the basis of health outcomes!

Question 15

Do you object to the government adjusting prices downwards (paraphrased)?

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Answer

Not if price volume agreements are negotiated or there are other relevant factors such (as often happens) drugs perform less well in the "real world" of actual clinical use than they did in the original clinical trials, or an alternative drug becomes available at a lower price, etc.

Question 16

Why do you propose that many existing arrangements mentioned in the FTA (such as Q15), to which you do not object, should be eliminated from the FTA by the Senate (paraphrased)?

Answer

Because these "cosmetic" provisions are packaged with others that are decidedly not "cosmetic" such as the unbalanced principles, the review process, the medicines working party, the IP provisions and the dispute resolution clauses! In addition, it is my understanding that the only option the Senate has with respect to the FTA is to oppose all FTA provisions by blocking the implementing legislation. However, if it was possible to remove the unobjectionable clauses relating to the PBS while leaving the truly "cosmetic" I would support that approach.

Question 17

What is wrong with putting some principles, with which you agree, into an international agreement (paraphrased)?

Answer

See answer to question 16 above. In addition, I do not believe that a social policy such as the PBS has any place in a bilateral FTA; especially with a country (the USA) which is openly using bilateral FTA's to negotiate TRIPS PLUS provisions that deny poor people in developing countries access to essential drugs. The Howard government has done Australia's reputation much harm in the international public health arena by signing this FTA with the USA and thus supporting US policy in this regard.

Question 18

What is the evidence that the IP provisions of the FTA could delay the introduction of generic drugs (paraphrased)?

Answer

See:

- Drahos P, Henry D. [Editorial] The free trade agreement between Australia and the United States: Undermines Australian public health and protects US interests in pharmaceuticals. BMJ 2004;328:1271-1272 (29 May), Available: http://bmj.bmjjournals.com/cgi/content/full/328/7451/1271?etoc

- Also numerous Senate FTA Inquiry submissions available at: http://www.aph.gov.au/Senate/committee/freetrade_ctte/submissions/sublist.htm e.g.
    - Submission 75. Generic Medicines Industry Association Pty Ltd.;
    - Submission 147. Australian Nursing Federation;
    - Submission 369. Public Health Association of Australia Inc.;
    - Submission 405. Catholic Health Australia;
    - Submission 407. Doctors Reform Society;
    - Submission 445. National Centre for Epidemiology and Population Health;
    - Submission 522. Australian Consumers' Association;

Question 19

On what evidence do you believe the Medicines Working Group "will lead to drug price hikes in Australia (paraphrased)?"

Answer

The medicines working group is yet another US strategy whereby pressure will be brought upon Australian DoHA officials to pay more attention to the principles of Annex 2-C (higher profits for American pharmaceutical companies) rather than PBS principles (equitable access to affordable drugs). Clearly, the US PhRMA published goal is to raise Australian drug prices.[7] It is naïve to think that the provisions they have inserted in the FTA, such as the medicines working group, are not part of that strategy.

In addition, as mentioned above In addition, once an item has been recommended for listing by PBAC the Health Minister has the power to change the listing criteria (for example by increasing the price as Minister Michael Wooldridge did with Celecoxib). Clearly, it will be possible for the Medicines Working Group to make similar recommendations to the Health Minister in line with to the principles of Annex 2-C.

Question 20

How can the working group change anything (paraphrased)?

Answer

Since there are no details about its operation (except the principles of Annex 2-C) we can only assume that it will attempt to implement those principles (see answer to question 19 above).

Conclusion

Our world-respected PBS is crucial to ensuring the continuance of an egalitarian and compassionate healthcare system in Australia. It is also an important international exemplar, particularly to many developing nations with large generic pharmaceutical industries.

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The PBS has no place in an FTA!

I support the many health and consumer organisations that have asked the Senate to block the amendments to legislation required to implement the FTA, either to block the FTA in its entirety or, if that is not possible, to produce a further exchange of letters between Australia and the US that clarify the matters set out in Table 1 (below) before agreeing to pass the necessary implementing legislation.

Dr. Ken Harvey
Amman, Jordan
13 June 2004

Declaration of Interest

I am a Senior Lecturer in the School of Public Health, La Trobe University, Australia with specific expertise in pharmaceutical policy. I am an international consultant in pharmaceutical policy to the Australian Health Insurance Commission (for which La Trobe University receives remuneration, not I). I have been a non-remunerated Board member of Therapeutic Guidelines Limited (and currently act as a consultant to that organisation). I am also a non-remunerated Councillor of the Australian Consumers Association. I derive no income from the pharmaceutical industry and have no relationship with it (except as an occasional critic).

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Table 1: Recommended clarification of the FTA concerning the PBS

- That in reference to the introduction of Annex 2-C Pharmaceuticals it is also agreed that, "This agreement shall be interpreted and implemented to protect public health and promote universal and affordable access to necessary medicines".
- That in reference to the "Agreed Principles" of Annex 2-C Pharmaceuticals it be also agreed that the following additional principles apply:
  (e) The need to ensure equitable and affordable access to necessary medicines.
  (f) The important role of generic manufacturers in protecting public health by providing price competition when patents have expired or in health emergencies.
- That in the event of a dispute all the agreed principles (including the above) are used as the interpretive framework.
- That the "review process" for PBAC decisions specifically states that it does not allow the overturning of PBAC decisions by the use of dispute resolution or other mechanisms.
- That the "review process" allows review of both "no" and "yes" decisions (the latter where, for example, leakage of effectiveness or affordability concerns has been established).
- That the "review process" can not only be instituted by pharmaceutical manufacturers but also by health professional &/or consumer organisations.
- That the "experts" involved in any PBAC "review process" are broadly representative of all PBS stakeholders: government, health professionals, consumers and the pharmaceutical industry.
- That the "Medicines Working Group" be fully transparent by posting all agenda items, discussion and recommendations on the PBS web-site.
- That in the interests of ensuring genuine rather than "selective" transparency in PBAC processes all documentation submitted by a pharmaceutical applicant is made available to the public on the PBS web.
- That the capacity of generic manufacturers to rapidly "springboard" their cheaper products from existing data upon the expiry of a patent be unequivocally protected.
- That an independent research study be jointly funded by both parties to determine the public health impact of implementing Clause 5 of Annex 2-C, "Dissemination of information by the Internet" and of all the FTA provisions related to the PBS.