

Free trade in pharmaceuticals

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In the spirit of free trade between Australia and the United States, we should work together on the healthcare policy issues facing our two countries. My previous contribution to the *Journal* unpacked the dismal US experience with general practice corporatisation, just as this trend was gaining momentum in Australia.¹ Australia, in turn, offers important lessons for the US. Americans are increasingly looking to “pay for value” in health-care.^{2,3} The Australian experience with the economic evaluation of drugs in the Pharmaceutical Benefits Scheme (PBS) is the “gold standard” of such programs worldwide. The US has much to learn from the Australian model — if only the drug companies don’t destroy the PBS first.

The PBS has generated unwelcome attention from both the Pharmaceutical Research and Manufacturers of America and Medicines Australia. This is not surprising, as the PBS economic evaluation goes hand in hand with some of the lowest patented drug prices in the developed world.⁴ After years of unsuccessful domestic attempts to derail the PBS in Australia, the Pharmaceutical Research and Manufacturers of America and Medicines Australia turned to international trade law, namely the Australia–US Free Trade Agreement (AUSFTA).

Provisions in AUSFTA concerning the PBS were added under the direction of Ralph Ives, the chief US negotiator. After his success in Australia, Mr Ives was promoted in April 2004 to the newly created post of Assistant United States Trade Representative for Pharmaceutical Policy. In his new post, he will attempt to raise patented drug prices throughout the world through trade agreements, even though there is no proof that higher prices are necessary to pharmaceutical innovation.⁵

Before this global crusade against the scourge of affordable prescription drugs spreads to Australia, I suggest a thoughtful and deliberate pause, pondering some points that may not have received the attention they deserve in Australia. There is no need to rush enactment of the Australian legislation for the US Free Trade Agreement Implementation Bill 2004.

Do not sacrifice the PBS to please America

AUSFTA was not negotiated with the US, but with Ralph Ives. America has not yet formed an opinion on the PBS issue. In contrast to the robust debate in Australia, the American public is only dimly aware of the PBS issue. Congressional debate was very limited when AUSFTA was approved by the US House of Representatives on 14 July 2004, and the Senate the day after. It was only recently that Congress discovered that AUSFTA forbade the export of cheaper Australian drugs to the US, something that a



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ABSTRACT

- Provisions in the Australia–United States Free Trade Agreement (AUSFTA) may threaten the Australian Pharmaceutical Benefits Scheme (PBS), the “gold standard” of such programs worldwide.
- If Australia postpones passing of the US Free Trade Agreement Implementation Bill in the Senate, there will be opportunity for broader interests in both the United States and Australia to carefully study the agreement.
- The provisions of AUSFTA relating to the PBS are supposed to promote transparency, but the pharmaceutical manufacturers themselves (who are demanding transparency) do not reveal the content of their submissions to the Pharmaceutical Benefits Advisory Committee, or disclose all their financial relationships with researchers and policymakers.
- In AUSFTA, the “public health” language of affordable prescription drugs is missing and is replaced by language supporting “pharmaceutical innovation”.
- Debate as to whether AUSFTA will force significant changes to the PBS, including higher drug prices, is currently under way in Australia. Perhaps the appropriate target of reforms should be the excessive US drug prices, and not the economically efficient Australian drug prices.

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majority of Congress supports.⁶ The ball is in Australia’s court to perform a thorough public vetting. If Australia postpones the passing of the US Free Trade Agreement Implementation Bill by the Australian Senate until after the US and Australian elections, opportunity would be given for broader interests and non-government organisations (NGOs) in both countries to carefully study the agreement. A hurried review serves only the interests of those who already have a thorough understanding of the document.

Look behind the transparency curtain

We are told that AUSFTA is needed to promote “transparency” in the Pharmaceutical Benefits Advisory Committee (PBAC) process.⁷

If transparency is the goal, let me suggest the first place to start: publicly release all of the submissions to the PBAC. Policymakers worldwide would benefit from seeing all of the data previously collected. If drug companies believe that they’ve been unfairly treated, then the debate can proceed publicly. Today, PBAC data in Australia are secret (“commercial in-confidence”) because the drug companies demand secrecy, even though some of these data may be available in other countries. Release the data publicly and allow the world to see the economic evaluations. Australia can achieve greater data transparency on its own initiative, without embracing the other aspects of AUSFTA.

Second, transparency should require drug companies to disclose all financial relationships with researchers and policymakers. The

US National Institutes of Health is currently embroiled in a major controversy, as we are just beginning to understand how profoundly the pharmaceutical industry influences research.⁸ We need transparency to ensure research independence. All of this is absent from AUSFTA.

Third, will transparency apply to the new Medicines Working Group under AUSFTA? Which federal officials will be appointed? Will the US practice of appointing industry members to act as “advisory committees” be followed? Will those meetings be open to the public? Will relevant NGOs be permitted to participate? Will past and present conflicts of interest be disclosed?

Finally, the very concept of “transparency” is not to be found in the 1000-page free trade agreement. This is a frightfully complex agreement, with minutely negotiated provisions that are very difficult for even trade lawyers to understand. For example, when the US stood against the world to attack unlicensed generic antiretroviral drugs for HIV/AIDS, it was the “public health” language of the WTO TRIPS agreement (World Trade Organization Agreement on Trade-related Aspects of Intellectual Property Rights) that rallied the world against the US and eventually led to the concessions at Doha and Cancun.⁹ In AUSFTA, the “public health” language is missing and is replaced by other language supporting “pharmaceutical innovation”. In the future, when the US invokes the AUSFTA dispute resolution mechanism, a panel of highly specialised trade experts will decide whether Australia’s efforts to reform the PBS satisfy AUSFTA. To these experts, the absence of the TRIPS public health language and the additional provision on pharmaceutical innovation will be viewed as very significant. Australia could well lose a panel decision on such a basis, allowing a government to plead years from now that its hands are tied by AUSFTA. I suspect that AUSFTA includes many other subtleties. It will take some time to find them all.

Prescribe large grains of salt with government pronouncements

The debate as to whether AUSFTA will force significant changes to the PBS is currently under way in Australia. While scaled back from early proposals, AUSFTA nonetheless requires subtle modifications to the PBS, which may lead to higher prices in Australia, as detailed by recent testimony in the Australian Parliament.¹⁰ It is not sufficient to merely review the terms of the US Free Trade Agreement Implementation Bill, as it ignores many required elements of AUSFTA. The American experience with laws of this sort is clear — pharmaceutical companies consistently use them to raise prices.

A recent study by the Centre for International Economics claims that the PBS provisions won’t raise drug prices at all in Australia.¹¹ If that is so, then why did the Pharmaceutical Research and Manufacturers of America and Medicines Australia lobby for the provision? Why is the entire free trade agreement being risked on this one issue? If there is truly no impact, then it should be removed immediately by a side letter. A majority of the US Congress may welcome a side letter resolving the exportation issue, as majorities of both the House of Representatives and the Senate voted for drug importation bills last year.¹² Silence from the drug companies speaks volumes.

A similar *non sequitur* arose under the “non-interference” provision that the Pharmaceutical Research and Manufacturers of America added to the US Medicare Modernization Act of 2003.¹³

This law commits the US federal government to purchase US\$600 billion in pharmaceuticals over the next decade, but prohibits the government from using its purchasing power to negotiate better prices. The Bush administration insists that this provision won’t raise prices at all.¹⁴ Of course it won’t!

Articulating the goals of the Pharmaceutical Research and Manufacturers of America, the then head of the US Food and Drug Administration (our version of Australia’s Therapeutic Goods Administration) proclaimed that drug prices in developed countries are too low and must be increased.¹⁵⁻¹⁷ Other observers might reach the opposite conclusion — that Australian drug prices are economically efficient and the appropriate targets of reform are excessive US drug prices.

Some parts of this article have been published in a *BMJ Rapid Response (Testimony to the US House Ways & Means Committee on the Australia-US FTA, bmj.com/cgi/eletters/328/7451/1271)* to the article *The free trade agreement between Australia and the United States*, by Peter Drahos and David Henry (bmj.bmjournals.com/cgi/content/full/328/7451/1271).

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