More Questions Than Answers:
A Quick Analysis of the USTR Press Release on the AUSFTA

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(my comments are in brackets)

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http://www.ustr.gov/new/fta/Australia/2004-07-08-factsheet-pharm.pdf

U.S.-Australia Free Trade Agreement: Questions and Answers About Pharmaceuticals

USTR
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What guidance has Congress given about pharmaceutical trade issues?

For decades, Congress set trade negotiating objectives that called for increased foreign market access for U.S. innovative medicines through tariff cuts and strong protections for U.S. intellectual property. In the Trade Act of 2002, Congress provided additional guidance with negotiating objectives that call for increased transparency in the pharmaceutical regulatory process, consultative mechanisms, and addressing non-tariff market access issues such as reference pricing.

> **[The Trade Act of 2002 calls for the "elimination of government measures such as price controls and reference pricing which deny full market access for United States products."[1] While Australia's system does not employ price controls, it does rely on reference pricing and the economic evaluation of drugs.]**

How has the U.S. been dealing with international pharmaceutical issues in trade agreements?

In earlier trade agreements, USTR worked to achieve congressional negotiating objectives with provisions that eliminated or reduced duties on U.S. pharmaceutical products, and with strong IPR provisions protecting patents for pharmaceuticals and other innovative U.S. products. Over the past few decades, market access and pricing issues
also have been part of the U.S. trade dialogue with Canada, Japan, Korea and China.

> **[Similar provisions are also found in the Free Trade Agreement for the Americas (FTAA), the Central American Free Trade Agreement (CAFTA), and Free Trade Agreements (FTAs) negotiated or in process with Israel, Singapore, Morocco, and Jordan. It also fails to mention that the promotion of the chief US negotiator of the**

[1] Trade Act of 2002, 107-210, §2102(b)(8)(D).

AUSFTA. After his success in Australia, Mr. Ralph 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 developed world through trade agreements,[2] even though there is no proof that higher prices are necessary to pharmaceutical innovation.[3]]

What are the key provisions regarding pharmaceuticals in the U.S.-Australia FTA?

Based on new guidance from Congress in the Trade Act of 2002, the Australia FTA was the first FTA to include specific provisions dealing with non-tariff market access issues related to pharmaceuticals. The Australia FTA achieves these objectives through provisions for increased transparency and accountability and enhanced consultation in the operation of Australia's Pharmaceutical Benefits Scheme (PBS). These provisions are based in large part on the Australian government's own studies.

The PBS already has a process for determining which drugs it will cover under its national health care program and the amount it will reimburse for these drugs. In the agreement, Australia committed to the principle of appropriately recognizing the value of innovative pharmaceuticals.

The U.S. and Australia also agreed to establish a Medicines Working Group to discuss emerging health policy issues.

[First, notice how the USTR gives credit for the initiative to Australia, and fails to say that prices won't be raised in Australia. Second, the Medicines Working Group is now broadened to 'emerging health policy issues' and may become a nexus for company lobbying. Will health experts and NGOs have the opportunity to counter industry lobbying of the Medicines Working Group?]

Does the U.S.-Australia FTA block imports of patented pharmaceuticals?

The FTA imposes no new barriers to imports but reflects current U.S. law, which gives any patent holder the right to control sales (including by contract) of its product in the United States. This right, a core principle of U.S. patent law for more than 100 years, applies to all U.S. patents, not just pharmaceuticals. For example, toothbrushes, tape dispensers, semi-conductors, printer cartridges, cameras, tools, and a vast assortment of other products covered by U.S. patents have all benefited from these rights. The FTA does not expand or diminish the current rights of U.S. patent holders. It simply reflects longstanding U.S. law in this area.

[This is a misleading statement. US law permits importation of certain gray market goods. See the famous Supreme Court case K Mart Corp. v. Cartier, Inc.,[4] and the

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[2] A clear outline of the Bush Administration's pharmaceutical trade agenda can be found in the testimony of Grant D. Aldonas, Under Secretary of Commerce for International Trade, to the US Senate Finance Committee on April 27, 2004.

[3] Outterson, K. Pharmaceutical arbitrage. Yale Journal of Health Policy, Law & Ethics 2004 Dec; 6(2) (pending) (discussing the concept of *globally optimal patent rents* in the context of pharmaceutical innovation).

[4] 486 US 281 (1988).

WTO TRIPS Agreement.[5] In the case of patented pharmaceuticals, the US law was unclear before this case was handed down, particularly for drugs originally produced in the US, so the industry sponsored the Prescription Drug Marketing Act of 1987 which forbade importation by anyone other than the manufacturer.[6] This is precisely the law which the re-importation bills in Congress seek to overturn.

My conclusion: the only purpose of the provision is to tie the hands of Congress, to prevent them from overturning the PDMA ban on re-importation and from otherwise blocking drug import legislation. It is disingenuous to suggest that it is an innocent addition to the FTA. In fact, the language does not appear in the FTA at all, but in a side letter, because USTR was concerned about the political fallout from a clear ban on importation. See the last paragraph as well.]

Does the U.S.-Australia FTA prevent Congress from passing drug re-importation legislation?

No. The FTA reflects current law in the United States. Nothing in this FTA or any other trade agreement prevents Congress from changing U.S. law in the future. Even if a dispute settlement panel found the U.S. acted inconsistently with the FTA, it could not require Congress to amend the law. Importantly, provisions in the FTA protecting patent holders' rights only apply to products under patent. This provision would have no impact on importation of non-patented (generic) prescription drugs.

[Highly misleading. Congress could pass laws that violate the FTA all day, but the US would be in violation of a treaty and under the provisions of the FTA, would be subject to sanctions, much as the NAFTA and WTO dispute resolution processes work.

As for generics, first, USTR's willingness to permit generics in undermines the 'safety' argument. The primary goal is to protect the profits of the PhRMA companies. Second, US generic drug prices are low through competition. We don't need imports of generics. Third, according to official Australian governmental reports, Australia's prices on patented drugs are among the lowest in the OECD, much lower than Canada, and even lower than the US federal supply schedule.[7] The AUSFTA provision blocks only the particular drugs that will save Americans money. Finally, some States are looking to save money by importing from Australia. For example, a preliminary report from the a state agency notes that tens of millions of dollars could be saved by importing the top 10 drugs used in West Virginia.[8]]

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[5] TRIPS specifically declines to adopt the 'domestic exhaustion' rule. TRIPS, art. 6.
[6] Prescription Drug Marketing Act of 1987, 21 U.S.C. §§ 331(t), 381(d) (2004).
[7] Productivity Commission (Australia). International Pharmaceutical Price Differences, July 2001. The Productivity Commission did not reach a definitive conclusion on causation.
[8] Draft report of the reference pricing subcommittee, West Virginia Pharmaceutical Cost Management Council, June 2004.

Does the U.S.-Australia FTA ban exports of pharmaceuticals from Australia?

No. Australian law, however, bans exports of pharmaceuticals if such drugs are purchased under Australia's Pharmaceutical Benefits Scheme (PBS).

> **[Highly misleading. Importers of drugs from Australia to the US would not have to purchase from PBS (this is akin to getting drugs under Medicaid and then reselling them). Importers can buy patented drugs in Australia from any drug store at prices that are much lower than US prices, without violating any PBS rule. When Australians buy drugs, they get them from drug stores, not the PBS. Exporters to America would not apply for PBS reimbursement.]**

Will the U.S.-Australia FTA raise the price of medicines in Australia?

The Government of Australia retains the right and authority to set the prices of medicine under the PBS. The provisions of the pharmaceutical annex to the Agreement will help improve market access for pharmaceuticals in Australia by improving the transparency and accountability of Australia's PBS system.

> **[Never answers the question. Public comments by the Bush Administration[9] and PhRMA reps[10] in prior months made clear that the goal was to increase Australian prices. Now they hedge, trying to dampen Australian public opinion until after the agreement is finalized.]**

Are any existing or future U.S. health care programs subject to the pharmaceutical provisions of the U.S.-Australia FTA?

USTR has worked closely with all relevant U.S. agencies to ensure the FTA does not require any changes to U.S. health care programs. Procurement of pharmaceutical products by the Veterans Administration (VA) and the Department of Defense (DoD) is excluded from the Pharmaceutical Annex of the agreement, and U.S. agencies already comply with other provisions of the FTA dealing with government procurement, so no change to current practice will be required.

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[9] McClellan M.B. Speech before the First International Colloquium on Generic Medicine. 2003 Sept. 25, available at http://www.fda.gov/oc/speeches/2003/genericdrug0925.html. The speech was widely reported. See, e.g., Bowe C., Dyer G. Americans lured by lower prices. Financial Times 2004 May 5, at 17. ("The rhetoric intensified in September when Mark McClellan, then head of the FDA, attacked European drug price controls and said other rich nations should pay more of the development cost for drugs."). See also Serafini MW. Drug prices: A new tack. National Journal 2004 Apr.17;36:16. ("So [US House Speaker] Hastert and [US Senator] Kyl championed the novel idea that the key to lowering U.S. prescription drug prices is to persuade foreign governments to raise their prices…The idea of trying to level the international playing field on prescription drug pricing originated with the U.S. pharmaceutical industry. But Hastert and Kyl played significant roles last fall in persuading the Bush administration to embrace this strategy…The result was the United States' first free-trade agreement that included modest concessions on pharmaceutical price controls.").

[10] The official US advisory committee on pharmaceutical issues in the FTA (the ISAC-3 committee) included representatives from Monsanto, Dow Chemical, Schering-Plough, Eli Lilly, S.C. Johnson and PhRMA. The only NGO represented was Friends of the Earth, which is an environmental group not involved in health care IP issues. See http://www.ustr.gov/new/fta/Australia/advisor/isac03.pdf.

Procurement of pharmaceutical products by state Medicaid agencies is excluded because coverage and reimbursement decisions are made by state officials, not by federal health authorities.

The FTA's transparency obligations may apply to certain pharmaceutical reimbursement decisions under Medicare Part B, and current Medicare practice is already consistent with the FTA. Medicare Part D, which will take effect in 2006, will not be covered since coverage and payment decisions are not directly made by Federal health authorities.

> **[I find it amazing that this provision, added by the insistence of PhRMA and USTR, over repeated objections and foot dragging by Australia, could in any way affect domestic US health care policy. This is a major issue! Australia didn't want the provision; PhRMA and USTR did; we added it to the AUSFTA and now it will affect our domestic law?? It sounds like the executive branch using the conduit of a treaty to block future domestic legislation (permanently) that it doesn't like. What a great Constitutional case on separation of powers.]**