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The U.S.-Australia Free Trade Agreement Can Preempt Drug Reimportation Bills, Challenge VA and Medicaid Drug Price Controls July 8, 2004

Summary

President Bush has sent Congress the text of the implementing legislation for the U.S.-Australia Free Trade Agreement. Supporters of the Agreement hope that Congress will consider it before the summer recess begins on July 23, according to Congress Daily.

The Australia Free Trade Agreement can affect US drug prices in three ways:

- 1. It prohibits reimportation of Australia's less expensive drugs into the US, and could preempt pending legislation on reimportation.**
- 2. Drug companies can challenge drug purchasing and reimbursement decisions by the Department of Veterans Affairs and other government authorities, which could lead to higher drug prices.**
- 3. Drug companies can challenge drug purchasing and reimbursement decisions by Medicare and Medicaid, which could lead to higher drug prices.**

According to many Australian health and public officials, the Agreement would compromise key elements of Australia's drug pricing system, resulting in higher pharmaceutical costs.

U.S. health care consumers and professionals are not represented in trade negotiations. Trade agreements, which frequently lead to unintended consequences, increasingly address important issues of health and social policy. Congress can take steps now to assure that the U.S.-Australia FTA protects affordable drug prices, and to include the public health community in a transparent trade policy process

Key Points

- 1. The Australia FTA prohibits reimportation of Australia's less expensive drugs into the US.**

Many members of Congress and the public have expressed interest in reimportation as a partial solution to unaffordable drug prices in the U.S. As CPATH reported in testimony to the House of Representatives on July 16, Chapter 17.9.4 of the Australia Free Trade Agreement on parallel importation would block reimportation of lower priced drugs into the U.S from Australia. Prior to that testimony, the US Trade Representative maintained that the provisions on reimportation had been removed from the Agreement.

Chapter 17.9.4 states:

Each Party shall provide that the exclusive right of the patent owner to prevent importation of a patented product, or a product that results from a patented process, without the consent of the patent owner shall not be limited by the sale or distribution of that product outside its territory, at least where the patentee has placed restrictions on importation by contract or other means.

In contrast to other language in the Agreement, which sets obligations the Parties (referring to countries) have with respect to each other, this section refers only to what each Party must do, with respect to patent holders. These patent holders include drug companies, as well as other kinds of companies. Because of the way it is worded, this provision arguably requires the U.S. to prohibit reimportation of drugs from any other country, if drug patent holders require it so do so.

This reflects current U.S. law with regard to patented medications (generic drugs are typically less expensive, and not at issue), and U.S. law can be changed by Congress. However, it would be extremely difficult for Congress to retroactively change this trade agreement once it is enacted. Under particular sections and annexes, each country is allowed to identify areas where current and future domestic legislation can differ from the Agreement. Section 102 protects current US laws, but not future laws. There is no reference in any chapter or its related schedules and annexes to excluding parallel importation of drugs, or pharmaceuticals, from the provisions of the Agreement. Responding to questions from Rep. Sander Levin at a Ways and Means hearing on June 23, John Veroneau, general counsel for the Office of the USTR, confirmed that new legislation on drug reimportation “could give rise to an inconsistency between U.S. law and a commitment under this trade agreement.”

By including this provision in the FTA, the reimportation ban would become a matter of trade law. It would also set a precedent for future trade agreements. Whether this provision would stand up to a trade challenge, or whether a trade challenge would be initiated, cannot be predicted. It is difficult to understand, however, why this provision continues to appear in the Agreement, given Congressional objections on one hand, and the USTR’s assertion on the other hand that it is virtually meaningless.

2. Drug companies can challenge drug listing and pricing decisions by the Department of Veterans Affairs. These challenges could lead to higher drug prices for veterans’ medications.

The VA system effectively achieves very low prices for medicines. The Deputy U.S. Trade Representative confirmed that the U.S.-Australia Free Trade Agreement does apply to the VA, the Department of Defense, and other federal agencies that procure pharmaceuticals, in a written response to questions posed by the U.S. Senate Finance Committee on April 27, 2004. These agencies are covered by Chapter 15 of the Agreement, on Government Procurement, which includes provisions on transparency, technical specifications, and independent review of agency procurement decisions.

(The USTR has also accurately stated that these agencies are not covered by a different section of the Agreement, Annex 2-C on Pharmaceuticals. This is a technical clarification with little significance. Annex 2-C applies to a different set of government agencies, as discussed below.)

Under Article 15.11 “suppliers” have the right to challenge VA procurement decisions, including listing and pricing pharmaceuticals. Suppliers are defined as businesses, according to the USTR.

15.11.1: “In the event of a complaint **by a supplier** of a Party that there has been a breach of the other Party’s measures...the Party of the procuring entity shall encourage **the supplier** to seek resolution of **its complaint** in consultation with the procuring entity.”

15.11.2: “Each Party shall maintain at least one impartial administrative or judicial authority that is independent of its procuring entities to receive and review **challenges that suppliers submit**, in accordance with the Party’s law, relating to a covered procurement.”

The independent review bodies must have the right to overrule VA decisions promptly; this is different from the current domestic bid challenge system.

15.11.4: “Each Party shall ensure that the authorities referred to in paragraph 2 **have the power to take prompt interim measures**, pending the resolution of the challenge, to preserve the supplier’s opportunity to participate in the procurement and to ensure that the procuring entities of the Party comply with its measures implementing this Chapter. Such interim measures may include, where appropriate, suspending the contract award or the performance of a contract that has already been awarded.”

An official of the Office of the USTR reported that the independent review procedure for VA procurement is intended to refer to the current system for bid challenges, which relies on the General Accounting Office and U.S. courts to adjudicate appeals. However, the GAO is not authorized to “take prompt interim measures” to overturn VA decisions; it can only make recommendations. Courts can overturn VA decisions, but access to the courts would probably not be considered “prompt.” On its face, the current bid challenge system does not seem to meet the requirements of the FTA for prompt suspension of a contract award.

A system that does meet these requirements could jeopardize the VA’s successful drug pricing system.

Grounds for filing a complaint do not need to include a charge of discrimination based on national origin. A drug company can be based anywhere.

Grounds for filing a complaint do not need to include a charge of discrimination based on national origin. A supplier that did not get a contract can assert **failure to comply with the Federal Acquisition Regulations**, in the case of the US, or corresponding national procurement law in the case of Australia. It can also assert violation of terms of the FTA, including the rules on transparency, or the technical specifications section which requires that decisions **do not have the “purpose or effect of creating unnecessary obstacles to trade.”** A drug company with an office in Australia could initiate a challenge.

VA drug procurement could be excluded from the Agreement.

Many procurement decisions are already excluded from both the Australia FTA and from the World Trade Organization’s Government Procurement Agreement, including motor vehicles and dredging at construction sites. In the WTO Agreement, the US has also exempted travel agencies, and telecommunications networks and services **Important government programs that provide benefits to millions, including vulnerable populations, can legitimately be added to the list of excluded measures.**

3. The Australia FTA gives rights to drug companies to challenge drug purchasing and reimbursement decisions by Medicare and Medicaid, which could lead to higher prices.

Annex 2-C on Pharmaceuticals applies to “federal healthcare authorities [that] operate or maintain procedures for listing new pharmaceuticals or indications for reimbursement purposes, or for setting the amount of reimbursement for pharmaceuticals, under its federal healthcare programs.” These programs are distinguished from others, that procure drugs directly, and are covered by Chapter 15 on Government Procurement.

The USTR has stated that parts of Medicare would be covered by this provision. Annex 2-C would also apply to Australia’s Pharmaceutical Benefits Scheme, which negotiates low drug prices for Australians.

The USTR has asserted that Medicaid would not be affected because it is a state program. However, a federal authority, HHS, maintains the federal statute on drug price rebates for Medicaid programs. (Many states then proceed to seek further discounts.) Medicaid was created by federal law and is generally regarded as a federal health care program. These are strong grounds for disputing the USTR's view.

Annex 2-C requires affected agencies to "make available an independent review process that may be invoked at the request of an applicant directly affected by a recommendation or determination." The USTR has stated that "applicants" refers to program beneficiaries. A May, 2004, request to the Department of Health and Human Services to clarify this point has not been answered.

Assuming that "applicants" includes drug companies, the California Senate Office of Research (SOR) has commented on the likely effects on Medicaid: "The...requirements that would appear to conflict with California current practice would be the independent review process, implemented at the request of an applicant, and the requirement that written justification for any decision be given to the applicant. In very general terms, the agreement would make drug pricing and regulation more difficult by expanding the basis for an applicant to challenge an administrative decision." The SOR explains that California, like most states, creates a "preferred drug list." Inclusion in the list "is accomplished through direct negotiations with the drug manufacturers...In California, the negotiations focus exclusively on prices...The negotiations on drug rebates are, at everyone's preference, carried out in secret and the individual arrangements are never made public. California permits any number of drugs to be added to the preferred drug list, if there is agreement on price." The SOR analyst agrees that failure to reach agreement on price could in this case be grounds for a request for independent review, a right that drug companies do not currently enjoy.

Congress can take steps now to change the U.S.-Australia FTA and to protect U.S. consumers.

Several provisions of the Agreement are ambiguous, including the definitions of the kinds of agencies covered, technical specifications, and independent review. Countries involved in trade disputes have frequently been surprised by the findings of trade dispute panels Government agencies that appeal these provisions in the event of a challenge, including by asserting that they are exempt, have no guarantee of prevailing.

These provisions have come as a surprise to most in the health, public health, veterans', and many other affected communities in the U.S. **There is no official representation for public health on any USTR advisory committee. Trade policy increasingly affects health and social policy. Trade negotiations must be transparent and democratic.**

Congress does not vote directly on the Agreement (which it cannot formally amend, due to fast-track procedures under the Trade Promotion Act of 2002). But Congress can communicate directly with the US Trade Representative and ask for changes prior to a vote. In addition, Congress does vote on the implementing legislation, which it can amend, and on the Statement of Administrative Action (SAA).

The implementing legislation could be amended to require approval by all relevant Congressional committees, including VA and health committees, as stated in the Trade Promotion Act.

The SAA could be amended to include statements the USTR has made to the Senate Finance Committee indicating the intention to exclude the Medicaid program.