Congress of the United States

Washington, DC 20515

July 11, 2004

The Australia FTA: The Facts About Provisions Relating to Prescription Drugs

The Precedent is the Concern

Dear Colleague:

We believe that each trade agreement must be evaluated in the context of the particular circumstances of the involved nation(s) and the likely impact on our businesses and workers. On these terms, we believe the Australia Free Trade Agreement (FTA) is worthy of support.

At the same time, we believe it necessary to be sure that the record is straight on how USTR approaches provisions on prescription drugs in the Australia FTA and how it could set a worrisome precedent for future FTAs.

Prescription Drug Provisions in the Australia FTA

When negotiating the Australia FTA, USTR sought to include a number of provisions that were designed to undermine Australia's universal drug coverage program (the Pharmaceuticals Benefit Scheme or PBS). A number of us Democrats and others raised concerns about these provisions, both because of their potential impact on Australia's efforts to provide prescription drugs to its citizens and because of their potential impact on the ability of U.S. programs – Medicare, VA programs, DoD programs, *etc.* – to provide prescription drugs in the United States.

In view of our objections and resistance by the Government of Australia, most of the provisions sought by the White House were not ultimately included in the FTA. There remain in the FTA two issues related to prescription drugs.

Government Programs Promoting Access to Prescription Drugs

One set of provisions in the FTA is designed to increase the transparency of and provide appeal rights related to government decisions associated with pharmaceuticals programs; these provisions apply to programs both in the United States and Australia. We have been told categorically by USTR that these provisions will not require any changes to the administration of U.S. programs to which they are applicable (including Medicare Part B). This fact has been reflected in the official Statement of Administrative Action, which notes that no changes to current U.S. law or administrative practice are required to implement these provisions of the agreement. However, the fact that a trade agreement can open up domestic health law, like Medicare, to potential changes is a concern.

Drug Re-importation

The Australia FTA also includes a provision that is related to the drug re-importation debate. **As discussed below, this provision will not have a practical effect due to the fact that Australia's domestic law prohibits the export of drugs purchased through its government-subsidized program, which accounts for over 90% of all drugs sold in Australia.**

However, it is important to take note of Article 17.9.4 of the Australia FTA so that it does not set a precedent for any future trade negotiations.

Article 17.9.4 of the Australia FTA essentially "codifies" existing U.S. law in an international trade agreement. Current U.S. law allows patent holders to bar the import of their patented products. This aspect of current law applies to patented prescription drugs.

In order to allow for the "re-importation" of patented drugs, the United States must change the current law. Drug re-importation bills like S. 2328 (which has a bipartisan group of

30 co-sponsors) repeal the current law rules that allow patent holders to bar the import of patented drugs, whether through patent or contract law.

Accordingly, were Congress to pass a bill like S. 2328 to allow for the import of patented drugs, the United States would be in technical violation of the U.S.-Australia FTA. **In the case of Australia FTA, the technical violation would be without practical effect for two reasons.** First, as mentioned earlier, Australian law already prohibits the export of drugs purchased through its government-negotiated program, which accounts for over 90% of all drugs sold in Australia.

Second, Article 17.9.4 matters only to the extent that the United States is allowing the import of prescription drugs from Australia or which are covered by a patent owned by an Australian firm. Imports from Canada and other OECD countries are generally not at issue. Therefore, as a practical matter, with or without the Australia FTA, there is little possibility of importing prescription drugs from Australia.

However, if the Australian model were applied to trade relations with Canada (where re-exporting is legal), it would allow legal challenges under trade law to free trade in drugs from Canada.

When Congress is actively debating a specific change to U.S. law, it is unwise to insert a provision into a trade agreement that might lead the U.S. to be in violation should we adopt the change. Yet, USTR has testified that the pharmaceutical provisions in the Australia FTA "lay the groundwork for future FTAs," which will "steer us in ongoing and future global, regional, and bilateral negotiations – including upcoming FTA negotiations and consultations with Canada and other major trading partners bilaterally and in international fora like the OECD." (Deputy USTR Josetter Shiner, Senate Finance Committee, April 27, emphasis added.)

Therefore, in supporting the U.S.-Australia FTA, **we hope you will join us in sending a very strong message to the USTR** that we reject use of the Australia FTA as a model or a precedent for any future trade negotiations.

Sincerely,

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