

NLARx

Legislative Working Group
Prescription Drugs & Trade

Forum
on democracy & trade

August 20, 2005

Ambassador Rob Portman
Office of the United States Trade Representative
600 17th Street, N.W.
Washington, DC 20508

Dear Ambassador Portman,

Thank you very much for your letter of July 27th. We appreciate your taking the time to respond to our earlier letter raising concerns about the potential impact of international trade commitments on state prescription drug purchasing and cost management programs. Your willingness to respond makes us hopeful that, with your leadership, communications between the states and USTR on matters of trade policy will be improved.

We appreciate the assurances contained in your letter, particularly the pharmaceutical provisions of the Australia-United States Free Trade Agreement (AUSFTA). Your letter states that “we also were careful to ensure that state programs or Federal programs that are implemented at the state level, such as Medicaid programs, are not covered by the Pharmaceutical Annex.” Your letter clarifies that it did not *intend* for Medicaid programs to be covered by the Annex. Nevertheless, the text of Annex 2-C remains ambiguous, as our letter of July 27th explained.

In order to avoid any potential misinterpretation by an international trade tribunal of the language currently found in Annex 2-C, we request, at the earliest possible date, that USTR work to memorialize its interpretation of AUSFTA’s Pharmaceutical Annex by issuing an interpretive note, which USTR would propose for adoption by the Joint Committee for administration of the AUSFTA under the provisions of Article 21.1(2)(e).

USTR is currently negotiating a bilateral FTA with the Kingdom of Thailand. Can you please inform us whether USTR intends to include a Pharmaceutical Annex, with similar or related provisions to that of AUSFTA’s Annex 2-C, as part of the FTA with Thailand? We look forward to your clarification of this matter.

Finally, regarding drug reimportation, we appreciate the statement that “the [Australia FTA] agreement neither expands nor diminishes the current rights of U.S. patent holders, and does not affect Congress’ ability to modify U.S. patent law in the future.” We would note, however, that our letter did not question whether or not a U.S. trade commitment would affect the current rights of patent holders, or would impact Congress’ ability to pass legislation pertaining to patent rights.

Legislative Working Group on Prescription Drugs & Trade
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We are aware that international trade commitments do not have an automatic effect on domestic U.S. laws, either at the state or local level; that only the federal government has the right to sue a state in domestic U.S. courts in order to invalidate state law; and that trade commitments do not impact Congress' *ability* to pass legislation of any kind. Rather, our concern is whether a pre-existing international trade commitment might impact Congress' *willingness* to pass legislation pertaining to patent rights.

We believe an international trade commitment would influence Congress if passage of legislation inconsistent with this trade commitment would expose the United States to potential sanctions. It is apparent that our concern in this regard was shared by some members of Congress, one of whom authored an amendment instructing USTR not to replicate AUSFTA-style language in future bilateral and regional trade agreements.

The Legislative Working Group on Trade & Prescription Drugs has been studying the impact of the AUSFTA, of GATS, and of other trade agreements on state health care programs. Your letter provides a useful starting point for further dialogue. The Working Group requests the opportunity to meet with USTR staff responsible for negotiations pertaining to pharmaceutical importation and purchasing. We believe it will be useful for your staff to obtain a better understanding of how state reimportation and Preferred Drug List (PDL) programs operate, and consequently why we are concerned about the content of AUSFTA's Pharmaceutical Annex, and the inclusion of similar provisions in other FTAs now under negotiation.

At the same time, we look forward to learning more about how USTR seeks to achieve the "balance between two critical public policy goals" noted in your letter, that is, access to medicines, and ensuring future pharmaceutical innovations.

Members of the Legislative Working Group would be available to meet USTR staff in Washington DC on October 20th, if that date is convenient. We would appreciate your earliest possible confirmation of that date and a time for a meeting, as our next opportunity to further federal-state dialogue on these issues of critical importance.

Thank you again for taking the time to write. Your response is deeply appreciated. With best wishes,

Yours sincerely,

Representative Kevin Ryan (CT) Representative Meg-Burton Cahill (AZ)
Co-Chairs, Legislative Working Group on Trade and Prescription Drugs

Senator Mark Montigny (MA)
Chair, National Legislative Association on Prescription Drugs (NLARx)

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