March 18, 2007

The Honorable Sander Levin
Chairman, Subcommittee on Trade
House and Ways and Means Committee
Washington, DC

Dear Chairman Levin and members of the Subcommittee on Trade:

We write to express our strong opposition to USTR's efforts to use provisions in the proposed US-Korea Free Trade Agreement (FTA) to undermine the use of drug formularies for managing prescription drug costs. On behalf of states across the nation that use similar formularies to contain drug costs for Medicaid and other programs that may be affected by the FTA language, we request you to seek assurances from USTR in the upcoming hearing on the US-Korea FTA negotiations that USTR will not include limitations on cost-cutting drug formularies in any final agreement.

Korea plans to use cost-cutting drug formularies in its national health system. So do a majority of U.S. states. The Legislative Working Group on Prescription Drugs and Trade, comprised of legislators from a number of states, strongly oppose inclusion of procedural or substantive standards in FTAs that threaten the operation and efficiency of these important public health programs.

Preferred Drug Lists (PDLs) are now in use in more than forty states for Medicaid and other programs. These are programs that, like Korea's positive list formulary, provide for price negotiations between pharmaceutical companies and the state as a condition of a drug's inclusion on a preferred list for reimbursement.

Use of PDLs has resulted in tremendous savings for cash-strapped states. Adjusted for inflation, Medicaid spending by state governments declined in 2005, while at the same time drug spending as a whole increased at double the rate of inflation. Similar tools are used by almost every bulk purchaser of drugs – including private insurance companies, branches of the U.S. federal government and most other industrialized countries. The President's budget for 2008 specifically noted that Medicaid "allows states to use [such] private sector management techniques to leverage greater discounts through negotiations with drug manufacturers."

We are extremely concerned that bilateral FTA negotiations with the Republic of Korea may endanger these successful state programs. USTR has repeatedly objected to plans by the Korean Ministry of Health and Welfare to institute a "positive list" of pharmaceuticals for which its National Health Insurance will reimburse patients' purchases. US Trade Representative Wendy Cutler publicly announced that Korea's use of the formulary was "inconsistent with both the mandate of the pharmaceuticals working group and the market opening spirit of the KORUS FTA."

Under the current version of Trade Promotion Authority, FTA provisions can preempt state law through suits by the Federal government. Thus, any provision in a US-Korea FTA that restricts or alters Korea's positive list may also threaten the operation of U.S. state PDLs. This may be the case even if the FTA provisions are procedural. Two of the requirements that USTR wishes to impose

on Korea's health services would (1) demand written justifications for decisions not to list a particular drug on the public formulary, and (2) allow pharmaceutical companies the right to appeal listing decisions. No member of the Working Group, and no state to our knowledge, currently offers such rights to pharmaceutical companies. These provisions, if applied to states, would create an enormous burden for state agencies whose primary concern is the timely delivery of essential medicines to patients.

Parts of the Federal Government have acknowledged the potential threat of USTR's stance to state programs. A State Department official noted in a diplomatic cable, released through a Freedom of Information Act request, that many U.S. States "are taking the same approach the [Korean government] is taking: containing costs by scrutinizing prescription drugs, particularly brand name drugs."

Two years ago, this Working Group raised a related set of concerns pertaining to the US-Australia Free Trade Agreement. We sought—unsuccessfully as it turned out—to receive binding assurances from USTR that provisions in Annex 2C of the US-Australia FTA would not restrict or alter state PDL programs. Similarly, California state Senators Liz Figueroa and Sheila Kuehl called on USTR "to make a precise, internationally-accepted interpretation of Annex 2C known to the states and to develop language in concurrence with Australia that explicitly excludes state and local government programs." This Working Group asked USTR to issue an "interpretive note" to formally ensure that state Medicaid programs are not covered under AUSFTA Annex 2C. In January 2006, the state senate of Vermont issued a Resolution urging USTR to pursue an exchange of interpretive notes with Australia. None of these requests have been honored by USTR.

USTR staff suggested last year that it would be difficult to change the provisions of the US-Australia agreement through an exchange of an "interpretive note." Still, we had reason to hope that, having heard from a number of states about their concerns, USTR would at a minimum refrain from negotiating similar provisions in future trade agreements, provisions that potentially can undermine the ability of U.S. state legislatures and public health departments to provide affordable medicines to our citizens.

We are extremely troubled by, and strongly oppose, USTR's efforts to alter public reimbursement formularies in the Korea FTA. We therefore request that you seek assurances from USTR that no provisions altering public drug reimbursement formularies will be included in the US-Korea Free Trade Agreement. For more information, please contact the Working Group's Executive Director, Peter Riggs, at 718-797-9472 or the Working Group's Counsel, Sean Flynn at 202-294-5749.

Sincerely,

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