STATE OF MAINE

Citizen Trade Policy Commission

February 24, 2014

The Honorable Michael Froman
United States Trade Representative
600 17th Street NW
Washington, DC 20508

Re: Comments concerning the pharmaceutical and medical device reimbursement and intellectual property provisions of the Trans-Pacific Partnership

Dear Ambassador Froman:

The Maine Citizen Trade Policy Commission (CTPC) is established in Maine State Law "..to assess and monitor the legal and economic impacts of trade agreements on state and local laws, working conditions and the business environment; to provide a mechanism for citizens and Legislators to voice their concerns and recommendations; and to make policy recommendations designed to protect Maine's jobs, business environment and laws from any negative impact of trade agreements." In seeking to fulfill its statutory mandate, the Commission voted unanimously during its meeting of February 24, 2014 to submit this letter to you regarding our views on the pharmaceutical and medical device reimbursement and intellectual property provisions of the Trans-Pacific Partnership.

The CTPC understands from several public reports that U.S. negotiators are now considering pharmaceutical reimbursement text in the TPP that would (1) use the pharmaceuticals annex in the Australia-US Free Trade Agreement (AUSFTA) as the drafting template rather than the provisions of the Korea-US agreement (KORUS); (2) specifically designate Medicare Part B as the only U.S. healthcare program subject to the rules of this Annex; (3) limit any appeals of reimbursement decisions to Medicare Part B beneficiaries; and (4) exclude text that may previously have been under consideration (according to leaked documents) that reimbursement decisions have a "transparent basis consisting of competitive market-derived prices in the party's territory".

The CTPC has never supported including pharmaceutical reimbursement provisions in any trade agreement, including AUSFTA, because these provisions reduce access to affordable medicines and insert policy into trade agreements that is best left to domestic regulation.[1] That said, the AUSFTA pharmaceutical annex raises fewer concerns than either KORUS or leaked TPP reimbursement text, and we are encouraged by USTR's apparent willingness to reconsider its earlier approach. In particular, we agree strongly with the opt-in approach that would specifically list any covered programs. The opt-in would clarify ambiguous text in

[1] See, eg, the CTPC's 2012 statutorily required biennial Assessment of the potential impact of trade policy on Maine's citizens, economy, laws and policies. The Assessment, posted online□here: http://www.maine.gov/legis/opla/CTPC2012finalassessment.pdf, concluded that the impact of the TPP reimbursement provisions on pharmaceutical pricing in Maine, and on access to healthcare, could be significant.

previous FTAs and insure that Medicaid, 340(B) and other pharmaceutical programs partially administered at the sub-central level by U.S. states are not bound by these rules.

As noted above, however, even the AUSFTA provisions raise concerns. The CTPC strongly urges the inclusion of the following provisions in any healthcare reimbursement and transparency annex in the TPP to address these concerns:

1. The Agreed Principles should specifically include language specifying that healthcare and medicines affordability, safety and efficacy are recognized criteria in government reimbursement decisions governed by the Annex.

2. There should be no appeal of reimbursement decisions but instead a review based on domestic law and limited to beneficiaries.

3. If applicants are afforded an opportunity to provide comments during the reimbursement decision process, beneficiaries and the public should also be allowed to provide comments.

4. Internet posting and other provisions relating to dissemination of information about pharmaceuticals must be bound by a Party's domestic laws and regulations. In other words, the provisions of the TPP must respect domestic policies concerning direct-to-consumer advertising and off-label marketing.

5. The Annex must specifically state that a decision regarding the listing of a pharmaceutical product or setting a reimbursement price through a program covered by the Annex may not be challenged under the country-to-country dispute settlement *nor under the investor-state dispute settlement provisions (ISDS) of the Chapter on Investments.* Both of these changes are critical, and the greater concern lies with the possibility that investors could use the ISDS to challenge these domestic policy decisions.

We also wish to reiterate the longstanding position of the CTPC that the TPP's Intellectual Property Chapter must balance encouraging innovation with assuring affordability. The publically reported USTR position pushing for a lengthy 12-year data exclusivity period for biologics is excessive and will significantly delay the development of generic versions of these pricey and life-saving medicines. The CTPC urges the USTR to modify its position to a more reasonable timeframe that will better protect the affordability of these important medicines.

Thank you for your consideration of these recommendations. The CTPC stands ready to discuss these recommendations with you and to respond to any requests for further information or clarification.

Sincerely,

Senator Troy Jackson, Chair

Representative Sharon Anglin Treat, Chair

cc:
Senator Susan Collins
Senator Angus King
Representative Michael Michaud
Representative Chellie Pingree
Kay Wilkie, IGPAC Chair
Rebecca Rosen, USTR, Director of Intergovernmental Affairs and Public Engagement
Barbara Weisel, USTR, TPP lead negotiator
Stanford McCoy, USTR, AUSTR for Intellectual Property and Innovation