April 30, 2014

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

Submitted electronically via correspondence@ustr.eop.gov, STATA@USTR.eop.gov

Dear Ambassador Froman:

The undersigned organizations appreciate our ongoing dialogue with your staff on prescription drug concerns related to the pending Trans-Pacific Partnership (TPP) trade agreement negotiations. While this dialogue has clarified a number of issues where we had questions, we continue to have substantive concerns that the TPP proposal, as we understand it, contains ill-advised provisions that could adversely affect U.S. prescription drug programs. We are writing today to reiterate these concerns in more detail, which center on the direction of the pharmaceuticals annex and how it would impact Medicare, as well as problematic provisions that the U.S. has proposed for inclusion in the intellectual property chapter. It remains our firm belief that the alteration of our nation's policies on Medicare reimbursement and patent standards should not be subject to binding provisions in international agreements like the TPP drafted through a process with little public transparency.

In general, we continue to be alarmed that the pharmaceuticals annex puts too much emphasis on drug industry priorities, and does not give equal weight to consumer priorities such as prescription drug affordability, safety, efficacy, and cost-effectiveness. To address this imbalance, we shared specific suggestions with your staff that we hope you will seriously consider adopting as part of the U.S. formal negotiating position on the annex. We strongly believe that consumer priorities, not drug industry priorities, should be the U.S. government's primary concern and encourage you to make every effort to address the current inequity in this regard as negotiations proceed.

We were pleased to learn from your staff that the current U.S. position is not to make the TPP pharmaceuticals annex provisions applicable to the operation of state Medicaid prescription drug programs, the Medicare Part D prescription drug program, or public health programs that utilize price negotiation such as the VA health program. However, national coverage determinations under Medicare Part B would be an expressly covered program and, consequently, would be subject to the annex's transparency and review commitments and bound by its policy restrictions. We strongly oppose this move that we believe could result in challenges to the payment methodology for Part B covered prescription drugs currently set at 106 percent of the average sales prices (ASP). Since shifting to the ASP in 2005, Medicare Part B drug spending has increased modestly at 2.7 percent per year, compared with increases of 25 percent per year between 1997 and

2003.[1] As an area where the U.S. government establishes pricing decisions, we are very concerned the current TPP proposal could be used by pharmaceutical companies to challenge the current Medicare B payment methodology, or its application in specific cases, which has had a measure of success in slowing spending growth.

As we have noted before, the TPP proposal could also limit the development of future policies. There is growing evidence that the ASP+6 percent payment methodology could be further improved to enhance cost containment efforts,[2] which will take on even greater importance as the high cost of specialty drugs including biologic medicines will make up an increasing percentage of overall drug costs in the future.[3] The recent release of comprehensive Medicare Part B physician reimbursement data underscores the need to reexamine payment methodologies for Medicare Part B covered prescription drugs.[4] According to the data, the high cost of prescription drugs is behind the highest billing trends, and these costs are borne directly by Medicare beneficiaries through increased cost sharing.[5] [6] [7]

Given this, we believe it is critically important that Congress retain the ability to adjust reimbursement policies for Medicare Part B covered prescription medicines unhindered by policy restrictions in the TPP. We are concerned a number of savings proposals could be restricted or foreclosed if the annex covers Part B, including current proposals that would:

- Lower the percentage paid by Medicare for Part B drugs from 106 percent to 103 percent of the ASP;

- Restore the legal authority for CMS to use a "least costly alternative" policy among competing Part B drugs;

- Require manufacturer discounts or rebates for Part B drugs; and

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[1] Medicare Payment Advisory Commission (MedPAC). 2012a. *Health Care Spending and the Medicare Program: A Data Book*, June 2012.

[2] J. Wilkerson, "Blum: CMS Eyes Cancer Drug Pay Reforms, Part D Spending Targets In ACOs," *InsideHealthPolicy*, December 11, 2012; P. Whoriskey, D. Keating, and L.H. Sun, "*Data Uncover Nation's Top Medicare Billers*," Washington Post, April 9, 2014.

[3] Express Scripts, *2013 Drug Trend Report*, April 2014; CVS Caremark, *2014 Drug Insights Report*, April 2014.

[4] Centers for Medicare and Medicaid Services (CMS), " Medicare Provider Utilization and Payment Data: Physician and Other Supplier," (April 2014), available at: http://www.cms.gov/Research-Statistics-Data-and-Systems/Statistics-Trends-and-Reports/Medicare-Provider-Charge-Data/Physician-and-Other-Supplier.html

[5] Whoriskey, P., "These maps tell you everything that is wrong with our drug pricing system," Washington Post (April 11, 2013), available at: http://www.washingtonpost.com/blogs/wonkblog/wp/2014/04/11/these-maps-tell-you-everything-thats-wrong-with-our-drug-pricing-system/.

[6] Whoriskey, P., Keating, D., and L.H. Sun, "Cost of drugs used by Medicare doctors can vary greatly by region, analysis finds," Washington Post (April 9, 2013), available at: http://www.washingtonpost.com/business/economy/cost-of-drugs-used-by-medicare-doctors-can-vary-greatly-by-region-analysis-finds/2014/04/09/69ac93f0-c024-11e3-b574-f8748871856a_story.html.

[7] Department of Health and Human Services, Office of the Inspector General (OIG), "Review of Medicare Part B Avastin and Lucentis Treatments for Age-Related Macular Degeneration," (September 2011), available at: http://oig.hhs.gov/oas/reports/region10/11000514.pdf; This OIG investigation revealed that Medicare beneficiaries would have saved $275 million in 2008 and 2009 had the federal government reimbursed for the least costly alternative among available macular degeneration medicines.

- Allow Medicare to negotiate drug prices in Part B for those drugs where the Medicare program purchases the majority of a particular drug or accounts for a large share of drug spending.

We strongly urge you to consider the implications of the pharmaceuticals annex for consumers as well as the financial sustainability of the taxpayer-funded Medicare program. *Any final agreement in the TPP must make it clear that parties may adopt substantive savings proposals to lower consumer costs and reduce government spending under their healthcare authorities without restriction or the possibility of challenge through international forums.*

As we have discussed with your staff, we are also concerned by proposals in the intellectual property chapter that would greatly expand international minimum standards for domestic patent protection beyond that included in the World Trade Organization's Agreement on Trade-Related Aspects of Intellectual Property Rights (TRIPS). This proposal, as we understand it, would lower the standards of patentability, which could hamper the efforts that TPP parties have made to curtail the problem of "evergreening" drug patents, particularly for products that do not demonstrate a clear, significant clinical advantage or efficacy over the reference product. We are also concerned the proposal would establish new requirements in international law to grant patents on diagnostic, therapeutic, and surgical methods, as well as new forms and uses of known products. These and other provisions could restrict the range of policy options that could be adopted by Congress to address the serious problem of patent "evergreening."

Our concerns also stem from the fact that expanding patentability criteria would be counter to ongoing efforts to reform U.S. patent standards to address the increase in overly broad patents that contribute to "patent trolling." More importantly, such efforts would directly contradict the development and implementation of restrictions on patentability, including the recent U.S. Supreme Court decision (*Association for Molecular Pathology v. Myriad Genetics, Inc.*) that isolating naturally occurring genes is not patent eligible subject matter.

For all these reasons, we request you withdraw proposed intellectual property chapter language that goes beyond the WTO TRIPS Agreement and would lower patentability criteria or restrict how governments can define patentable subject matter and patentability criteria.

Thank you for considering our comments. We look forward to your response to the issues raised in this letter. If you or your staff members have any questions, please do not hesitate to contact us.

Sincerely,

AARP
AFL-CIO
American Federation of State, County and Municipal Employees
Alliance for a Just Society

Alliance for Retired Americans
Center for Medicare Advocacy, Inc.
Center on Budget and Policy Priorities
Consumers Union
Medicare Rights Center
National Committee to Preserve Social Security and Medicare
National Senior Citizens Law Center