

December 4, 2014

The President  
The White House  
Washington, DC 20500

Dear Mr. President:

We are grateful for your commitment to expanding health coverage and your work to protect and preserve Medicare, Medicaid and other health programs. But we write today to express our deep concern that provisions being advanced in negotiations for the Trans-Pacific Partnership Agreement (TPP) and the Trans-Atlantic Trade and Investment Partnership Agreement (T-TIP) could undermine the sustainability of U.S. health programs and block efforts to improve them in the future.

In particular, our concerns are centered on negotiations related to patent rules, reimbursement policies for pharmaceutical drugs and medical devices, and the application of investor-state dispute settlement to government administered health programs.

Reports by UNITAID<sup>i</sup> and others indicate that the U.S. is pursuing patent provisions in the TPP agreement that would further delay generic market entry and competition for brand-name pharmaceutical drugs. Among the proposals reported are patent linkage requirements, further patent extensions for administrative delays and the inclusion of data exclusivity measures for chemical drugs. Other reported proposals include a twelve-year data exclusivity period for biologics and a requirement that patents be extended for small changes in drug formula or administration that do not improve a drug's efficacy, a practice known as evergreening. Including such provisions in trade agreements could block future Congresses from taking steps to encourage more competition and reduce federal and state spending.

With respect to reimbursement policies in public programs, we urge that the U.S. not pursue provisions similar to those included in free trade agreements reached with Australia and Korea. Overall, the provisions in these agreements lack balance, emphasizing the need to reward innovation over the need to ensure the safety of products and their affordability for taxpayers and program beneficiaries. So-called "transparency" provisions would provide manufacturers with additional leverage and opportunities to boost reimbursement rates. Under Korea-type pricing and listing provisions, preferred drug lists, statutorily specified rebates and discounts, and utilization rules could be challenged as trade violations by global corporations.

With respect to investor-state dispute settlement (ISDS), we have deep concerns about this enforcement mechanism because it would allow global pharmaceutical firms to challenge mechanisms that state legislatures, the Congress and public agencies use to manage pharmaceutical costs in public programs. Global corporations have become much more aggressive in the use of ISDS in recent years<sup>ii</sup> and researchers report that the ISDS process tends to protect corporate interests rather than the public interest.<sup>iii</sup> Moreover, trade tribunals are not required to track U.S. law or even abide by the U.S. Constitution when making decisions that

impact U.S. citizens. Federal and state policy makers must have the ability to manage costs in health programs without fear that international trade arbitrators will force the federal government to compensate global pharmaceutical and medical device manufacturers for reduced profits.

We appreciate that international trade has the potential to improve the lives of the people of the U.S. and around the world. But for trade to be beneficial to ordinary Americans, it must not undermine a need as central to their well-being as their health care security. Patent rules and reimbursement policies must be the product of a democratic process that allows all stakeholders to participate. The President and governors, Congress and state legislatures are the appropriate authorities for this decision-making and U.S. courts, not international trade tribunals, are the appropriate venue for adjudicating disputes. As negotiations over the TPP and T-TIP agreements move forward, we urge you to ensure that these agreements do not limit the tools available to policy makers to keep our health programs financially sustainable to serve current and future generations.

Thank you for considering our concerns.

Respectfully,

Alliance for a Just Society  
American Federation of State, County and Municipal Employees  
American Medical Student Association  
American Public Health Association  
Center for Medicare Advocacy  
Communications Workers of America  
Community Catalyst  
Consumers Union  
Medicare Rights Center  
National Alliance of State and Territorial AIDS Directors  
National Committee to Preserve Social Security and Medicare  
National Physicians Alliance  
NETWORK  
Service Employees International Union  
Universities Allied for Essential Medicines

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<sup>i</sup> UNITAID, The Trans-Pacific Partnership Agreement: Implications for Access to Medicines and Public Health (2014), available at [http://www.unitaid.eu/images/marketdynamics/publications/TPPA-Report\\_Final.pdf](http://www.unitaid.eu/images/marketdynamics/publications/TPPA-Report_Final.pdf)

<sup>ii</sup> United Nations Conference on Trade and Development, Recent Developments in Investor-State Dispute Settlement (ISDS), Updated for the Multilateral Dialogue on Investment, 28-29 May

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2013, (May 2013), available at  
[http://unctad.org/en/PublicationsLibrary/webdiaepcb2013d3\\_en.pdf](http://unctad.org/en/PublicationsLibrary/webdiaepcb2013d3_en.pdf)

<sup>iii</sup> Van Harten, G., “Pro-Investor or Pro-State Bias in Investment-Treaty Arbitration? Forthcoming Study Gives Cause for Concern,” *Investment Treaty News* (April 13, 2012), available at <http://www.iisd.org/itn/2012/04/13/pro-investor-or-pro-state-bias-in-investment-treaty-arbitration-forthcoming-study-gives-cause-for-concern/>