

AFL-CIO

GPhA
Generic Pharmaceutical Association

AARP
Real Possibilities



December 16, 2014

President Barack Obama
The White House
1600 Pennsylvania Avenue NW
Washington, DC 20500

Dear Mr. President:

The organizations signing this letter want to express our deep concerns regarding some of the provisions under negotiation in the Trans Pacific Partnership (TPP). These provisions could seriously impact access to affordable medicines by delaying generic competition as well as impacting governments' ability to advance public health policies in the U.S and around the world.

While we have different perspectives and interests, we are united by our shared concerns regarding access to affordable medicines and the need to ensure competition in the pharmaceutical market in the U.S. and abroad.

The interests at stake in this negotiation cannot be overstated, as the TPP will affect millions of people currently living in the twelve TPP negotiating countries, and will set new precedents in global trade policy. With important unmet public health needs, pressure on public health care expenditures and a growing aging population in the U.S., protecting patients' access to affordable medicines is of paramount importance here as well as throughout the world. Changes to the text currently under consideration in the TPP are required in three main areas.

First, the intellectual property (IP) provisions that the U.S. Trade Representative (USTR) has proposed fail to strike a proper balance between fostering innovation and ensuring expedited access to more affordable generic drugs through increased competition in the pharmaceutical market. They would also undermine biomedical innovation by restricting access to science and medical knowledge. The latest leaked text of the IP Chapter dated May 16, 2014 reveals proposals that would not only require TPP parties

to grant very high levels of IP protection that go beyond existing international trade commitments, but would also lock in policies, for example with respect to biologic pharmaceuticals, that would contribute to putting these very expensive drugs and vaccines out of the reach of patients. This would seriously undermine efforts to constrain growing government budgets and improve health outcomes. It requests the granting of secondary patents and also puts in place a provision for patent linkage that would effectively prevent generic manufacturers from launching many products regardless of the validity or non-infringement of a patent. As drafted, these and other IP provisions could lead to “evergreening” and the abuse and misuse of intellectual property rights, creating significant obstacles for generic competition.

Undermining the terms of competition for generic drugs will have several negative consequences. Some of the letter's signatories are concerned that it will injure export-dependent jobs among U.S. generics manufacturers, and all of us are concerned that the provisions would exacerbate the struggle to provide affordable, effective generic medicines--no matter where produced--to people in need, no matter where they live.

The IP provisions are especially concerning as the USTR is deviating from its stated support for the “May 10th” agreement, an important precedent set by the last bilateral free trade agreements (FTAs) signed with Colombia, Panama and Peru, which we recommend should be used as the basis for the TPP. The “May 10th” agreement, reflected in these prior FTAs, would provide a minimum common denominator for all countries that would strike a better balance to promote both innovation and expedited access to affordable drugs.

Second, while we all support the principle of greater transparency in trade negotiations, the demands included in the leaked draft text of the Annex on Transparency and Procedural Fairness for HealthCare Technologies (the Annex) could jeopardize governments' efforts to contain costs in publicly supported health care programs. We continue to be alarmed that the Annex puts too much emphasis on the priorities of the originator industry, and does not give equal weight to patients and public health priorities such as drug affordability, safety, efficacy, and cost-effectiveness. Indeed, this proposed text could have a negative impact on cost containment mechanisms, such as preferred drug lists, rebates, discounts, and formularies in all countries. For example, it could adversely impact formularies and utilization rules used in U.S. health care programs, including Medicare, Medicaid, the Veterans Health Administration, the TRICARE program, and the 340B Drug Pricing Program.

Third, some of the letter's signatories are concerned that Investor State Dispute Settlement (ISDS) proposals in the Investment Chapter could be used to limit competition, by allowing originator pharmaceutical firms to challenge efforts to manage pharmaceutical spending in public programs, including those used by state legislatures, Congress and public agencies here in the U.S. and abroad. For example, a manufacturer could challenge a state's Medicaid preferred drug list or utilization rules that limit access to a certain drug under specific circumstances. If adopted, some of your own budget proposals to control prescription drug spending could be subject to an ISDS challenge.

Since TPP is a regional trade agreement with global implications, the potential for challenges by originator pharmaceutical firms over a range of policies that seek to contain drug prices and promote competition is enormous. As the number of ISDS claims continues to grow, the threat of these types of claims is likely to have a chilling effect on new laws or regulations to control the growth of drug costs and promote competition in public programs.

We have individually conveyed our concerns to the USTR on multiple occasions. We sincerely hope that the U.S. will take into account our concerns as the TPP negotiations proceed into their final stages, to ensure that trade commitments entered into by the U.S. do not undermine legitimate generic competition, access to affordable drugs or public health policies, whether here in the U.S. or around the world.

Sincerely,



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CEO, AARP



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Raymond C. Offenheiser
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CC: The Honorable John Kerry, Secretary of State
The Honorable Jack Lew, Secretary of the Treasury
The Honorable Penny Pritzker, Secretary of Commerce
The Honorable Sylvia Mathews Burwell, Secretary of Health and Human Services
The Honorable Michael Froman, United States Trade Representative

The Honorable Ron Wyden, Chairman, Committee on Finance, United States Senate

The Honorable Orrin Hatch, Ranking Member, Committee on Finance, United States Senate

The Honorable Dave Camp, Chairman, Committee on Ways and Means, United States House of Representatives

The Honorable Sander Levin, Ranking Member, Committee on Ways and Means, United States House of Representatives