

**Congress of the United States**  
**House of Representatives**  
**Washington, D.C. 20515**

October 19, 2011

The Honorable Ron Kirk  
United States Trade Representative  
600 17th Street, NW  
Washington, DC 20508

Dear Ambassador Kirk:

As you start the next round of negotiations in Peru on the intellectual property chapter of the Trans Pacific Partnership (TPP), we are writing to underscore the importance of upholding the U.S. commitment to advancing an agreement that safeguards access to medicines in the developing world.

We are concerned that some of the goals and approaches described as part of the new strategic initiative Trade Enhancing Access to Medicines (TEAM)<sup>1</sup> could limit, rather than expand, access to medicines in poor countries. For example, we are concerned that the seemingly laudable goal of “driving” rather than “allowing” access to medicines, as exemplified in the so-called “TPP access window,” would instead simply result in further delays in marketing of generic medicines.

The best way to preserve our developing country trade partners’ access to medicines is to incorporate into the TPP the Bipartisan Agreement on Trade Policy of May 10, 2007.<sup>2</sup> The May 10 agreement, which was incorporated into Free Trade Agreements (FTA) with Peru, Colombia, and Panama, included a number of key modifications from prior FTAs “aimed at further ensuring that developing country free trade agreement partners are able to achieve an appropriate balance between fostering innovation in, and promoting access to, life-saving medicine.”<sup>3</sup> A core objective of these changes was to ensure that FTA obligations do not put patients in poor countries in a position in which they could have to wait longer than patients in the United States to obtain affordable life saving generic medicines.

Among the key changes, exclusive marketing rights based on clinical trial data were limited to one five-year period that could run concurrently with such protection in the United States. In addition, the FTA requirement to grant patent extensions became optional and regulatory authorities were given greater freedom to approve generic medicines by having patent disputes resolved through the legal system instead of the drug approval process.

---

<sup>1</sup> Office of the United States Trade Representative, *Trans-Pacific Partnership Trade Goals to Enhance Access to Medicines*, September 2011 (online at [http://www.ustr.gov/webfm\\_send/3059](http://www.ustr.gov/webfm_send/3059)).

<sup>2</sup> Office of the United States Trade Representative, *Bipartisan Agreement on Trade Policy*, May 2007 (online at [http://www.ustr.gov/sites/default/files/uploads/factsheets/2007/asset\\_upload\\_file127\\_11319.pdf](http://www.ustr.gov/sites/default/files/uploads/factsheets/2007/asset_upload_file127_11319.pdf))

<sup>3</sup> *Id.*

Furthermore, language was incorporated to make clear that our FTAs do not and should not prevent countries from taking measures to protect public health by promoting access to medicines for all. All these changes were designed to promote greater access to the necessary life saving drugs while maintaining adequate incentive for continued innovation.

Maintaining the flexibility provided by the May 10 provisions is critical for those TPP partners in the developing world that cannot afford to protect the public health. This includes Peru, which should not be pressured to give up the May 10 flexibilities contained in its existing FTA with the United States, and Vietnam, where an estimated 290,000 people are living with HIV/AIDS. The U.S. President's Emergency Plan for AIDS Relief (PEPFAR) supports 31,000 of the only 37,995 who are receiving anti-retroviral (ARV) treatment.<sup>4</sup> There would be significant concern if action through TPP could delay access to generic medicines which may result in higher costs to the U.S. government to reach PEPFAR treatment goals or could result in removing patients from treatment. Since Fiscal Year 2004, PEPFAR has spent over \$323 million in Vietnam to support comprehensive HIV/AIDS prevention, treatment and care and the UN Global Fund, which also receives U.S. government support, currently contributes approximately \$27 million per year.<sup>5</sup> We cannot squander this investment.

The strain of rising pharmaceutical costs also extends to non-communicable diseases, the leading causes of preventable death and disability responsible for over 60% of global deaths, 80% of which occur in developing countries.<sup>6</sup> Millions of people today in the developing world lack access to life-saving medicines. An expert commissioned by the United Nations has estimated that "improving access to existing medicines could save 10 million lives each year. Access to medicines is characterized by profound global inequality: fifteen percent of the world's population consumes over ninety percent of the world's pharmaceuticals."<sup>7</sup> It is essential that our trade agreements enable our partners in the developing world to address these growing challenges.

Thank you for attention to this important issue. As TPP negotiations move forward, we look forward to working with you to preserve key medicines-related aspects of the May 10 Agreement necessary for developing countries.

---

<sup>4</sup> See U.S. Department of State, *Partnership to Fight HIV/AIDS in Vietnam* (online at <http://www.pepfar.gov/countries/vietnam/index.htm>) and The Global Fund to Fight AIDS, Tuberculosis and Malaria, *Vietnam –Grant Portfolio* (online at <http://portfolio.theglobalfund.org/country/index/vtn?lang=en>).

<sup>5</sup> See *Id.*

<sup>6</sup> See World Health Organization, *Moscow Declaration Preamble*, First Global Ministerial Conference on Healthy Lifestyles and Noncommunicable Disease Control, April 2011 (online at [http://www.un.org/en/ga/president/65/issues/moscow\\_declaration\\_en.pdf](http://www.un.org/en/ga/president/65/issues/moscow_declaration_en.pdf)).

<sup>7</sup> UN News Centre, *UN Rights Expert Unveils Draft Guidelines for Drug Companies on Vital Medicines*, UN News Centre, Oct.25, 2007.

The Honorable Ron Kirk  
October 19, 2011  
Page 3

Sincerely,



Henry A. Waxman  
Ranking Member  
Committee on Energy  
and Commerce



Sander M. Levin  
Ranking Member  
Committee on Ways  
and Means



John Conyers, Jr.  
Ranking Member  
Committee on the Judiciary



Jim McDermott  
Ranking Member  
Subcommittee on Trade,  
Committee on Ways  
and Means