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December 1, 2011

The Honorable Ron Kirk  
United States Trade Representative  
600 17<sup>th</sup> Street, NW  
Washington, D.C. 20508

Dear Ambassador Kirk:

I write to express my strong objection to the apparent reversal of United States trade policy during negotiations on the Trans Pacific Partnership (TPP) Agreement with respect to ensuring access to medicines for our developing country trade partners.

As you are aware, the Bipartisan Agreement on New Trade Policy of May 10, 2007 (May 10 Agreement), includes provisions to ensure that developing country free trade agreement partners are able to access life-saving medicines. A principal objective was to ensure that free trade agreements would not make matters worse for disadvantaged patients in developing countries by further delaying their access to affordable generic medicines.

I join other members of Congress in calling for improvement of the USTR's position in this negotiation, including the incorporation of the May 10 Agreement provisions to achieve more flexible test data protections and the elimination of proposed mandatory patent term extensions. The following principles should be incorporated into the TPP Agreement:

- The WTO Doha Declaration on the TRIPS Agreement and Public Health principles apply to all diseases and medical conditions, including non-communicable diseases;
- TPP standards should be flexible and reflect the diverse economies and public health systems among the developed and developing partner countries;
- The scope of patentability provisions should not force countries to patent new forms of old products without increase in therapeutic efficacy;
- The TPP should not prohibit pre-grant patent opposition; and
- The TPP should not undermine current or prospective, non-discriminatory drug reimbursement policies and programs in the United States (e.g. Medicare, Medicaid, VA, and other safety net programs) or in other countries.

Alarming, the Trade Enhancing Access to Medicines (TEAM) white paper released by the USTR on September 12, 2011, does not mention the May 10 Agreement, and in fact discards its goals, reflecting stale thinking about trade and access to medicines. Regrettably, it appears to serve the very familiar goals of the brand-name pharmaceutical industry, which knows no bounds in its zeal for profits, even when it comes to allowing fair generic competition that allows poor people in the developing world to afford life-saving medicines.

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The disingenuously named initiative does not balance trade with access to medicines. Rather, it would erect even higher intellectual property barriers to affordable generic medicines for millions. For example, the so-called "access window" it proposes would in fact close-off access by lengthening the time before affordable generics become available in each country as a result of lengthened data exclusivity periods and other monopoly entitlements that would be granted to brand name drug companies. The purported benefit, available only to those developing nations that rely on registration by referral, would be illusory as the brand name pharmaceutical manufacturers would not even be required to actually register the drugs in the developing nations but would become entitled to patent linkage, patent term extensions, and data exclusivity simply by initiating registration.

Furthermore, the TEAM initiative would grant new rights to pharmaceutical companies to challenge pricing and other drug formulary policies used by many developed countries to control rising prices. In the United States, for example, this would threaten a law that enables safety-net hospitals and clinics to provide access to low-cost life-saving drugs to millions of low-income and disabled Americans (section 340B of the Public Health Service Act).

The TEAM initiative is an alarming reversal of the United States' prior commitments to the goals of increasing access to affordable medicines for people of developing countries. Therefore, I urge you to reconsider this approach, to instead pursue at a minimum the incorporation of the May 10 Agreement into the Intellectual Property Chapter of the Trans Pacific Partnership, and to reject language that would prevent any country from taking measures to protect public health by promoting access to medicines for all of its citizens.

Finally, I firmly believe that the public has a right to monitor and express informed views on proposals of such magnitude as the TPP. While I recognize that some opportunity has been provided for the public to make presentations to delegates, I urge you to make the negotiating text of the TPP available to the public for review and comment. Without access to the actual texts being discussed, in my view the effective input and informed participation of the public is severely curtailed.

I look forward to discussing these concerns with you in the near future.

Sincerely,



Bernard Sanders

United States Senator