Congress of the United States

Washington, D.C. 20515

August 2, 2011

Ambassador Ron Kirk
Office of the United States Trade Representative
600 17th Street NW
Washington, DC 20508

Dear Ambassador Kirk:

Access to safe, affordable medicines is critical to improving global health and global security. In difficult economic and budget times, it is especially important that we promote trade policies that allow governments to protect their populations, especially in developing countries where life-saving medications are essential to protecting the health of millions of people. We are concerned about reports that your office is promoting provisions that move away from recent agreements designed to improve access to affordable medicine. We would like to request a meeting with you to discuss those concerns and, in particular, the approach that your office is considering for the Trans-Pacific Partnership (TPP) Trade Agreement negotiations that would undermine public health and access to medicines in the developing countries negotiating that agreement.

Expanding access to health for those in need has been a centerpiece of U.S. foreign policy in the Obama administration and previous administrations. The WTO TRIPS Agreement contains safeguards and other flexibilities that maintain the balance between protection of intellectual policy (IP) and public interest in health. In 2001, the U.S. joined other WTO Members in unanimously adopting the Doha Declaration on TRIPS and Public Health, which affirms that the TRIPS Agreement "can and should be interpreted and implemented in a manner supportive of WTO members' right to protect public health and, in particular, to promote access to medicines for all." The President's Emergency Plan for AIDS Relief and the Obama Administration's Global Health Initiative have made access to life-saving medicines a key element in saving lives and improving global security and are largely reliant on generic medicines for sustainability. The 2007 bipartisan "May 10th Agreement" was an important step in moving U.S. trade policy back toward a more balanced approach to promoting innovation and health in trade agreements with developing countries.

We are concerned about reports that the balance is once again shifting away from the progress achieved in those past efforts away from access to affordable medicines and towards the greater protection of intellectual property rights for brand-name pharmaceutical companies in the developing world, a move that would jeopardize treatment goals and millions of lives.

In recent years, the United States has interpreted the Doha Declaration narrowly, negotiating IP chapters in FTAs with developing countries that expand IP protection by restricting governments' use of the safeguards and flexibilities in TRIPS. These so-called "TRIPS-plus" measures prolong the monopoly period for originator drugs and delay competition from generic medicines, which is critical to affordability. TRIPS-plus provisions in FTAs have been demonstrated to dramatically increase the cost of medicines in developing countries, pricing medicines out of reach of the poor and straining public health budgets.

We believe the May 10th agreement should be a starting point for U.S. negotiating positions on patent linkage, patent extension, and data exclusivity in FTAs with developing countries, including the TPP. Instead, it appears that you are prepared to move away from that agreement and go far beyond both the letter and the spirit of the Doha Declaration and the May 10th Agreement by re-introducing measures modified under that Agreement and by introducing new IP and pharmaceutical measures that will hinder access.

We have heard that the U.S. proposal on IP could include several TRIPS-plus provisions on IP protection and enforcement that would undermine access to affordable medicines. These issues are important not only for ensuring that medicines are available in TPP countries but also can be produced for export to countries even more in need—in Africa, Asia, and Latin America. Specifically, we understand that:

- The U.S. may propose expanding data exclusivity requirements, which restrict marketing approval for generic medicines even in the absence of a patent. We would urge that the May 10th agreement be the starting point of negotiations, and in general, we would urge any data exclusivity provisions, if included at all, be made voluntary, expire no later than a comparative period in the U.S., and include public health safeguards.

- The U.S. has sought to expand the scope of patentability to perpetuate monopolies even in the absence of any significant benefit to patients. Such a patentability standard goes beyond the requirement of the TRIPS agreement and could prevent or delay the entry of affordable generic options. We would ask, in the spirit of the May 10th Agreement, to remove such provisions and allow countries to establish their own WTO-compliant patentability standards.

- The U.S. has proposed *prohibiting* so-called "pre-grant opposition" which allows interested parties—public health experts, patient groups, and others—to present information before a patent is issued. We feel it is not appropriate for the U.S. to ask that TPP countries prohibit this essential democratic input, a move which would ultimately make patent examination less informed and result in improvidently granted patents, and ultimately increase the number of cases before the courts.

- A "pharmaceutical chapter" may be developed that would limit the ability of governments to negotiate with drug makers and set reimbursement rates. Such provisions are inappropriate in an FTA that includes developing countries.

Ensuring access to generic medicines in developing countries is important for citizens of those countries, and it is also in the interest of the United States. We worry that the long-term goals of public health and other programs in TPP countries would be challenged by such provisions, particularly in Vietnam, which was among the original PEPFAR focus countries.

We would also urge, in order to ensure that the U.S. approach to the TPP represents a broad range of views, that the negotiating text be released to facilitate public input. We recognize the difficult balancing act that you must achieve between competing interests in this trade negotiation. Yet we do not think the public health concerns facing developing countries have been effectively addressed. Greater public input, facilitated by the release of text, would facilitate additional feedback on key public health issues, including considering additional public health provisions that would improve access to medicines.

We look forward to your response and working with you to ensure that the U.S. priority of promoting health around the world through expanded access to affordable medicines is achieved.

Sincerely,

Rep. Jan Schakowsky

Rep. John Conyers

Rep. Donald Payne

Rep. Rosa DeLauro

Rep. Maxine Waters

Rep. Lynn Woolsey

Rep. Jesse Jackson, Jr.

Rep. Barbara Lee

Rep. Raúl Grijalva

Rep. Michael Michaud