Congress of the United States
House of Representatives
Washington, DC 20515

November 10, 2005

The Honorable Robert J. Portman
United States Trade Representative
600 17th Street NW
Washington, DC 20506

Dear Mr. Ambassador:

As the conclusion of the U.S.-Andean Free Trade Agreement approaches, we have serious concerns that the intellectual property (IP) standards for pharmaceuticals established by this and other recent agreements could severely undermine the balance between innovation and access to medicines and affordable health care both in the United States and abroad. The Andean FTA will be one of the first agreements completed under your leadership. We urge that you take this opportunity to set a course that will promote both drug innovation and the health of those living in the United States and the Andean nations.

In 1984, in enacting the Hatch-Waxman Act, Congress recognized the need to balance the protection of intellectual property of pharmaceuticals with the promotion of access to affordable medicines through a streamlined process for generic competition. Yet, recent FTAs disregard the access component and promote only the protection of innovation.

For example, as reported in the Colombian press in September 2004, the Administration has pushed for the inclusion in the Andean FTA of numerous provisions aimed at protecting innovation, including measures that would: (1) expand patent coverage to include diagnostic, therapeutic and surgical methods for the treatment of humans or animals; (2) provide "*at least*" five years of market exclusivity to manufacturers of new medicines independent of patent protection; (3) provide patents for new uses of patented products; (4) require national drug authorities to serve as the enforcers of drug patents, and (5) impose restrictions on a country's ability to allow parallel importing of patented drugs. Some of these provisions could facilitate the adoption of protections far beyond those provided in U.S. law. Further, imposing such IP provisions in countries that do not currently have a legal and regulatory framework comparable to that of the United States will serve only to undermine access to affordable medicines in these countries.

In contrast, the Administration has failed to include provisions that would promote greater access to affordable medicines, such as: (1) a "Bolar-type" provision to ensure that countries permit testing and experimental work required for the registration of a generic medicine during the patent period of the original product so that generics can enter the market immediately after the expiration of the patent; (2) a requirement that patentholders disclose the "best mode" for reproducing an invention so that society can benefit from it after the patent expires; or (3) caps on patent extensions for delays in the issuance of a patent or the marketing approval process.

Recent FTAs negotiated by this Administration also fail to take into account an even more basic reality. The reality is that IP provisions developed and tailored for the U.S. health care system may be entirely inappropriate for poor countries where few have access even to government clinics, let alone to private hospitals, pharmacies or heath insurance.

We have long supported strong IP provisions in free trade agreements. However, such provisions, as they relate to pharmaceutical innovation, also must foster access to affordable medicines. Our FTAs must uphold, at a minimum, the essential balance in U.S. law between promoting innovation and affordable health care and must respect the unique public health needs of our trading partners. We urge you to ensure that the USTR promotes these principles in trade negotiations so that FTAs do not put affordable health care at risk, at home and abroad.

Sincerely,

The Honorable Henry Waxman
Ranking Member
Committee on Government Reform

The Honorable Charles B. Rangel
Ranking Member
Committee on Ways and Means

The Honorable Pete Stark
Ranking Member
Subcommittee on Health
Committee on Ways and Means

The Honorable Sander Levin
Ranking Member
Subcommittee on Social Security
Committee on Ways and Means

The Honorable Jim McDermott
Ranking Member
Subcommittee on Human Resources
Committee on Ways and Means

The Honorable John Lewis
Ranking Member
Subcommittee on Oversight
Committee on Ways and Means

The Honorable Xavier Becerra
Member
Committee on Ways and Means

The Honorable Lloyd Doggett
Member
Committee on Ways and Means

The Honorable John Larson
Member
Committee on Ways and Means

The Honorable Rahm Emanuel
Member
Committee on Ways and Means

The Honorable Jan Schakowsky
Ranking Member
Subcommittee on Commerce, Trade,
and Consumer Protection
Committee on Energy and Commerce

The Honorable Sherrod Brown
Ranking Member
Subcommittee on Health
Committee on Energy and Commerce

The Honorable Linda Sanchez
Member of Congress

The Honorable Tom Allen
Member of Congress

The Honorable Bernie Sanders
Member of Congress