

Open Letter to the Honorable Charles Rangel on Access to Medicines and the US-Peru and US-Colombia Trade Agreements

January 17, 2007

Dear Honorable Chairman Rangel:

We are gravely concerned by the potential impact of intellectual property provisions in the US-Peru and US-Colombia Free Trade Agreements (FTAs). These provisions, which far exceed international standards for intellectual property protection established by the World Trade Organization (WTO), threaten to reduce access to essential medicines for people with life-threatening diseases, including HIV/AIDS, in Peru and Colombia. We understand there are efforts underway to reexamine provisions in these FTAs regarding labor standards and the environment. Given the grave impact the intellectual property provisions in these FTAs could have on access to medicines and public health, it would be a mistake not to take corrective action regarding the those provisions, as well.

The new intellectual property protections in these two FTAs would expand the monopoly rights of pharmaceutical companies that restrict generic competition and increase the cost of new medicines. These measures, which go beyond the terms of the WTO's TRIPS Agreement, could jeopardize poor Peruvians and Colombians' access to medicines, undermining the human right to health. Specifically, the Agreements:

- Require countries to grant exclusive rights, for at least five years, to brand-name companies to use the data they generate to show their product is safe and efficacious. The result will be to delay the introduction of generic medicines in some instances, keeping drug prices higher, for longer periods of time. These new requirements will also bar compulsory licensing -- the key means to speed up generic competition and reduce prices -- while so-called data exclusivity protections remain in place;
- Require countries to link the ability to obtain regulatory approval to sell a drug to the drug's patent status. Under "linkage" provisions, drug regulatory agencies are prohibited from granting regulatory approval to generic firms while brand-name companies claim a patent on a product. These measures turn drug regulatory agencies into patent police -- a function they are not equipped to handle. Similar provisions in U.S. law have been subject to serious abuse -- enabling brand-name companies to improperly delay generic competition -- as even the Bush administration has acknowledged. The United States, however, at least has a legal structure that affords generics an opportunity to challenge patents' validity -- an option typically not available or practicable in developing countries.
- Require countries to adopt patent extensions to offset delays in patent or regulatory approval. Such measures discriminate against generic competition, and require consumers for a longer period of time to buy the patented product from the patent owner for a longer period of time, or not at all. Even assuming that the delay in granting the patent or marketing approval was due to poor performance by the national patent office or drug regulatory agency, using patent term extensions as a remedy requires that consumers -- innocent third parties -- pay the price for the agencies' delays.

These provisions also violate the 2002 Trade Promotion Authority Act, which specifically instructs the United States Trade Representative (USTR) to respect the Declaration on the TRIPS Agreement and Public Health (the "Doha Declaration") in the course of trade negotiations. The Doha Declaration, to which the United States is a party, specifies that intellectual property rules should not prevent countries from protecting and promoting public health and access to medicines for all.

Only one-half of all Peruvians are covered by health insurance and one-fifth of the population has no access to health care. Medicines account for one-quarter of all public health expenditures and 44% of household spending on health. In Colombia, 45 percent of the population lacks adequate access to medicines, either because they have no health insurance or because the coverage they have does not include the medicines they need. Those unable to pay out of pocket for treatment costs receive no treatment at all.

A study of the projected impact of the US-Peru FTA commissioned by Peru's Ministry of Health found that the US-Peru FTA's increased monopoly protections for multinational pharmaceutical companies would significantly increase the price of medicines, thus burdening Peru's already overstretched public health care system and individuals suffering from poor health.

The Peru and Colombia FTAs, like all FTAs negotiated by the United States, were negotiated secretly and without including public health representation on USTR trade advisory panels. These panels, which are mandated by federal law to be balanced in their representation, instead rely upon biased guidance delivered by pharmaceutical industry representatives. Throughout the negotiations, USTR has consistently ignored warnings issued by concerned Americans, Peruvians and Colombians concerning the likely effect of the Peru and Colombia FTAs on the affordability of medicines.

Because of these provisions, which pose serious risks to the health of poor people in Peru and Colombia, we urge you to vote no on the US-Peru and US-Colombia FTAs unless they are renegotiated to exclude intellectual property protections for medicines that exceed the requirements established by the WTO TRIPS Agreement. Furthermore, any trade agreement with Peru, Colombia or other developing country should expressly include language in the text of the agreement that permits the use of all TRIPS-compliant flexibilities to protect public health and promote access to medicines for all, and ensuring that provisions related to pharmaceutical test data will not prevent licensing and registration of medicines produced or imported lawfully pursuant to such flexibilities.

Sincerely,

ActionAid International USA, Washington, D.C.
African Services Committee, Harlem, New York
Community HIV/AIDS Mobilization Project (CHAMP), Providence, Rhode Island
Gay Men's Health Crisis (GMHC), Manhattan, New York
Essential Action, Washington, D.C.
Health GAP (Global Access Project), Manhattan, New York
Oxfam America, Washington, D.C.