Congress of the United States
Washington, DC 20515

September 30, 2004

The President
The White House
Washington, DC

Dear Mr. President:

We are writing to express our strong opposition to the inclusion of provisions in pending free trade agreements (FTAs) with four Andean countries, five Central American countries, the Dominican Republic, and Panama that would restrict access to generic drugs. We believe that provisions in these agreements or under consideration for inclusion violate the requirement in Section 2101(b)(4)(C) of the Trade Promotion Authority Act of 2002 to uphold the 2001 *WTO Declaration on the TRIPS Agreement and Public Health* ("Doha Declaration") and additional protocols on its implementation.

The fundamental purpose of the Doha Declaration was to clarify that trade rules on intellectual property do not interfere with the ability of developing countries to take "measures to protect public health." The Doha Declaration clearly reaffirmed the right of WTO Members to use parallel imports and compulsory licenses to promote access to medicines. The flexibility to use such measures can be extremely important for countries struggling with HIV/AIDS and other serious diseases, where new brand-name medications may be priced out of the reach of those suffering.

Despite the consensus reflected in the Doha Declaration, your Administration appears to be seeking bilateral and multilateral agreements that undermine its important protections. We are specifically concerned about the inclusion of intellectual property restrictions in U.S. bilateral free trade negotiations with developing countries in Latin America, and elsewhere, that would grant five to eight years of exclusivity for brand name pharmaceutical products, even where patent barriers no longer exist. During that time governments would not be able to rely upon clinical test data submitted by the brand name products to grant marketing approval for generic copies, even in situations of urgency.

While similar periods of marketing exclusivity have successfully been used in the United States to promote innovation and enhance the availability of lower-cost drugs, they were part of a carefully balanced compromise introduced at a time when generics were not available in the United States. Moreover, these steps were coupled with measures to facilitate the approval of generics and accelerate competition in the marketplace. The situation is very different in the developing world. In Latin America, countries already have access to a robust generic market and there is no benefit, and the potential for serious harm, for them to delay that access. Furthermore, these countries have large rural and uninsured populations who pay out-of-pocket for drugs and could be entirely shut out of the healthcare system or left to use unsafe products from the black market if fewer generics are available.

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For any patient, five years without access to affordable drugs can be the difference between life and death. The prospect is especially dangerous for those with chronic or high-risk diseases. In the 11 Latin American countries that are our current FTA negotiating partners there are already more than 530,000 documented HIV/AIDS cases and an alarmingly low number of patients with access to treatment.

So far, your Administration is not addressing these concerns directly. The U.S. Trade Representative has refused to include explicit exceptions to protect public health or references to the Doha Declaration in the text of trade agreements. Ambassador Zoellick has instead proposed the use of side letters, similar to the one put forward in Dominican Republic-Central America FTA and the Morocco FTA, to indicate that the proposed intellectual property requirements "do not affect a Party's ability to take necessary measures to protect public health by promoting access to medicines for all." During consideration of the Morocco FTA, efforts were undertaken in the hearing and mark-up of the implementing legislation to make clear that the side letter serves as an exception to the intellectual property provisions in the FTA. USTR should not continue to use side letters in FTAs with language that needs to be resolved through legislative history. The language in the FTA itself must be clear and specific that, in order to meet the public health needs of their citizens, countries may continue to use the flexibilities explicit in the Doha Declaration, including parallel imports and compulsory licenses, and implicit in the consensus underlying that Declaration, such as reliance on otherwise-protected clinical test data.

We urge you to preserve the ability of Latin Americans and all of our trade partners in the developing world to obtain affordable, life-saving medicines, in a timely and efficient way and ensure that our FTAs uphold and respect the spirit and intent of the Doha Declaration.

Sincerely,

Hilda L. Solis
Member of Congress

Henry A. Waxman
Member of Congress

Charles B. Rangel
Member of Congress

Ciro D. Rodriguez
Member of Congress

Sherrod Brown
Member of Congress

Sander M. Levin
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