## Congress of the United States Washington, DC 20515

April 7, 2006

Ambassador Rob Portman United States Trade Representative 600 17th Street NW #508 Washington, D.C. 20508-0001

## Dear Ambassador Portman:

We are writing to inquire about the process of CAFTA-DR implementation. U.S. implementing legislation for CAFTA-DR conditions its entry into force on the President's determination that our trading partners have fulfilled their required commitments to implement the agreement. However, in the case of Guatemala, we are concerned about news reports that USTR is requiring additional reforms to those explicitly included in the text of the agreement before the President will allow its entry into force for that country. We are particularly concerned about such requirements in the area of intellectual property affecting pharmaceuticals.

Fifty six percent of Guatemalans live in poverty, less than a quarter of the population is covered by health insurance, the national budget for health care is one of the lowest in Latin America and most people, particularly the poor, must pay for medicines out of pocket. The U.S. should prioritize trade policies that ensure greater access to affordable medicines in Guatemala.

The intellectual property provisions in CAFTA-DR already require Central American countries to expand the patent monopoly rights afforded to originator companies to market their pharmaceutical products in these countries, which will delay or limit generic competition. Central American countries are already in compliance with the WTO's Trade Related Aspects of Intellectual Property Rights (TRIPS) Agreement, which presented a burden for low-income developing countries. Furthermore, Guatemala enacted a series of additional intellectual property rights protections just one year ago, upon USTR insistence, in order to prepare for CAFTA implementation.

In fact, Guatemalan intellectual property law now states that "In case of a discrepancy between provisions contained in this Law and those contained in trade agreements in force in Guatemala, the application of the latter will prevail with regard to the parties to the agreement" (Law 30-2005, article 7). Now there are news reports of USTR insisting on even more reforms to Guatemala's intellectual property and health regimes.

Among the reported changes to Guatemalan law that go beyond the CAFTA-DR mandates are:

- expanding the scope of what is considered a new product and is, thus, subject to data exclusivity;
- increasing the regulatory requirements for generics to gain marketing approval;
- allowing for patent or data protection for new clinical applications for existing medicines.

Enforcement of the provisions in U.S. trade agreements must be limited to the explicit commitments made in these agreements. Enforcement should not be viewed as an opportunity to rewrite another country's legislation and regulations. The dispute settlement chapter of agreements provides mechanisms to deal with any alleged lack of compliance by trading partners.

It would be potentially harmful to U.S. relations with Guatemala for USTR to insist that Guatemala reform its laws or regulations to enact any provisions that are not explicitly stipulated in the CAFTA-DR text. This is especially true because these provisions could cause Guatemala's intellectual property laws and regulations to be even more restrictive than those in the U.S. If other countries with which the U.S. is engaged in trade negotiations believe that USTR will continue to insist on additional intellectual property reforms even after a trade agreement is completed, signed and ratified, and even though they could be required to take on intellectual property protections that are stricter than those in the U.S., they may come to see the U.S. as an unreliable trading partner.

We respectfully request that you precisely detail the reforms USTR is requesting that Guatemala enact, through legislative or executive decrees or regulations, with regard to intellectual property rights and how these reforms relate to the explicit commitments assumed in CAFTA-DR. Furthermore, we expect USTR will refrain from insisting that Guatemala undertake any additional reforms in the area of intellectual property rights that could be interpreted as being outside of the explicit commitments assumed by all parties in CAFTA-DR.

We look forward to your response.

Sincerely,

Dennis J. Kucinich

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