



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

January 26, 2005

The Honorable Robert B. Zoellick  
United States Trade Representative  
600 17<sup>th</sup> Street, NW  
Washington, DC 20508

Dear Mr. Ambassador:

We are writing to follow up on letters sent to you on December 10, 2003 and September 30, 2004, opposing the inclusion of "test data" secrecy or pharmaceutical market exclusivity provisions in the free trade agreement with five Central American countries and the Dominican Republic (DR-CAFTA). In addition to other provisions that are problematic to us in this Agreement, we believe that inclusion of test data secrecy/market exclusivity provisions in the DR-CAFTA violates congressional direction under Trade Promotion Authority and is inappropriate as a policy matter.

An overwhelming majority in the Guatemalan Congress recently voted to repeal a law providing test data secrecy. The law had been in effect for only 18 months, having been enacted primarily due to pressure from USTR. The Pan-American Health Organization and UNICEF both publicly supported repeal of that law. Recent news reports have indicated that USTR has been pressuring Guatemala to reinstate this law. We request that you immediately cease pressure on Guatemala to adopt test data secrecy/market exclusivity and instead agree to remove this provision (relevant portions of Article 15.10) from the DR-CAFTA.

Section 2101(b)(4)(C) of the Trade Promotion Authority Act of 2002 directs USTR 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 ensure that trade rules on intellectual property do not interfere with the ability of developing countries to take "measures to protect public health ... and to promote access to medicines for all."

Inclusion of test data secrecy/market exclusivity provisions in an FTA with small, relatively poor developing economies such as the DR-CAFTA countries interferes directly with this central purpose of the Doha Declaration. Under the test data secrecy/market exclusivity rules, the DR-CAFTA countries are effectively required to prohibit for five years generic competition to brand name drugs, even where patent protection does not exist. Further, unlike patent protection, there is no clear exception to the test data secrecy/market exclusivity rules – creating uncertainty as to whether drugs produced under a compulsory license, but subject to test

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data secrecy, may be granted marketing approval even in public health emergencies. Accordingly, the test data secrecy/market exclusivity rules will slow the introduction of generic drugs, decrease competition, raise prices, and hinder access to life-saving medicines in the DR-CAFTA countries.

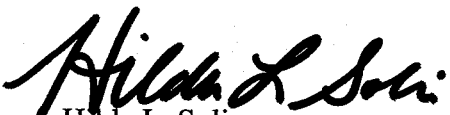
While similar periods of test data secrecy/market exclusivity have successfully been used to promote innovation and enhance the availability of lower-cost drugs in the United States, these rules were part of a carefully balanced compromise that included new measures to facilitate the approval of generic drugs and accelerate competition in the marketplace.

The situation is very different in the DR-CAFTA countries. These countries already have access to a robust generic drugs market. Further, because the countries' markets are so small, there is no significant trade advantage to the United States and no significant impact on global research and development expenditures if these countries provide test data secrecy/market exclusivity. Instead, there is a potential for serious harm to people in these countries who need access to affordable, life-saving drugs. The prospect is especially dangerous for a country like Guatemala, which has the largest number of people infected with HIV/AIDS in Central America, and other highly indebted CAFTA countries that cannot afford to divert their limited health care budgets to pay higher costs for brand name drugs.

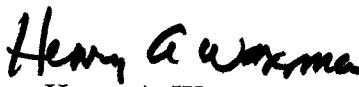
DR-CAFTA clearly erodes countries' protections under the Doha Declaration. The side letter to the DR-CAFTA on public health measures does not adequately address our concerns. During consideration of the Morocco FTA, efforts were undertaken in the hearing and mark-up of the implementing legislation to make clear that a similar 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 such legislative history. The language in the FTA itself must provide a clear and specific exception from the intellectual property and investment obligations for actions taken to meet important public health needs. Further, USTR's current effort to pressure Guatemala to change its law belies USTR's assurances that the side letter guarantees the right of the DR-CAFTA countries to address the public health needs of their citizens.

We look forward to your addressing this critical issue.

Sincerely,



Hilda L. Solis  
Member of Congress



Henry A. Waxman  
Member of Congress

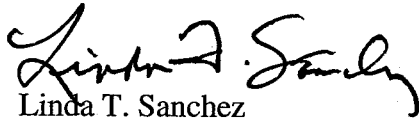


Charles B. Rangel  
Member of Congress

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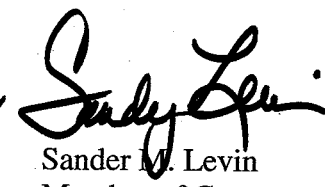
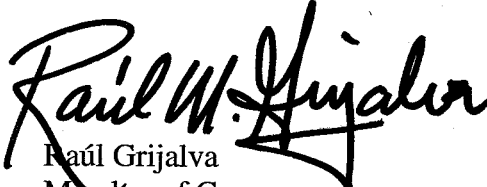
Linda T. Sanchez  
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Pete Stark  
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Sherrod Brown  
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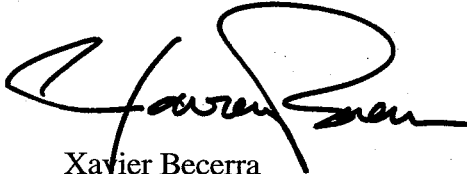


Raúl Grijalva  
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