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

December 10, 2003

The Honorable Robert B. Zoellick
United States Trade Representative
Winder Building, 600 17th Street, NW
Washington, DC 20508

Dear Mr. Ambassador:

We are writing to express our strong opposition to the inclusion of marketing approval restrictions for pharmaceutical products in the Central America Free Trade Agreement (CAFTA). Specifically, we understand that USTR is proposing to include a provision that would preclude generic alternatives from obtaining regulatory marketing approval based on approval granted for a brand name drug in that market, or another market, for a 5-8 year period. (For ease of reference, we refer to the provisions as "marketing exclusivity" requirements.) We believe that imposing such a requirement on *developing countries* will stifle the pharmaceutical marketplace, impede access to and availability of drugs, and drive drug prices to unaffordable levels for many in Central America.

The United States has successfully used a limited period of marketing exclusivity to enhance the availability of lower-cost drugs. It has been done, however, in conjunction with measures to accelerate the approval of generic alternatives. As you know, marketing exclusivity was granted to pharmaceutical companies in return for a new program under which low-cost generic drugs became available to Americans for the first time.

The situation in Central America is very different. First, the Central American countries already have access to a robust generic market and will receive nothing in exchange for delaying that access. Second, unlike the United States, the CAFTA countries have large rural and uninsured populations who pay out-of-pocket for drugs. Many Central American consumers could become entirely shut out of the healthcare system if fewer generics were available. For any patient, particularly those with high-risk diseases, five years without access to affordable drugs can be the difference between life and death. The prospect is especially dangerous considering that four of the six countries with the highest HIV/AIDS prevalence in Latin America are in Central America, rising rates of untreated diabetes and heart disease are already crippling, and the highly indebted CAFTA countries cannot afford to divert their limited health care budgets to pay for higher drug costs.

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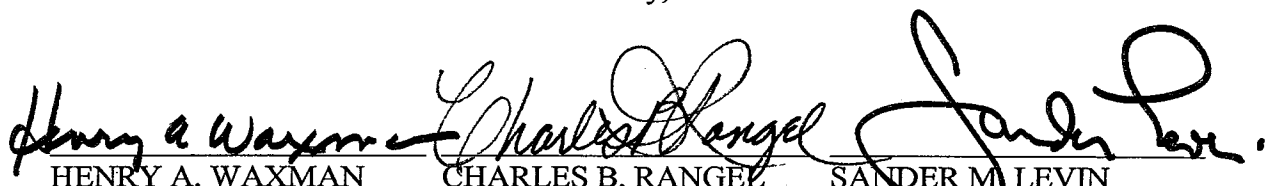
Delaying the introduction of generic competition for 8 years or more - even where patent barriers no longer exist – is inappropriate for developing countries facing these challenges. We urge you to strike the articles of the CAFTA agreement requiring 5- and 3-year marketing restrictions for pharmaceutical products and ensure that the people of Central America retain their right to affordable, life-saving medicine, in a timely and efficient way.

Sincerely,



HENRY A. WAXMAN
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House Committee on
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CHARLES B. RANGEL
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SANDER M. LEVIN
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