MEDECINS SANS FRONTIERES
DOCTORS WITHOUT BORDERS

333 Seventh Avenue, 2nd Floor
New York, New York 10001

Tel: 212.679.6800
Fax: 212.679.7016

doctors@newyork.msf.org
www.doctorswithoutborders.org

OPEN LETTER CONCERNING INTELLECTUAL PROPERTY AND ACCESS TO MEDICINES IN THE US-CENTRAL AMERICAN FREE TRADE AGREEMENT (CAFTA)

October 15, 2003

Ambassador Robert Zoellick
U.S. Trade Representative
Office of the U.S. Trade Representative
Washington, DC 20508

Sent Via E-mail to FR0060@ustr.gov and via Facsimile Transmission to 202-395-4549

Dear Ambassador Zoellick,

We are writing on behalf of Doctors Without Borders/Médecins Sans Frontierès (MSF) in advance of the Houston round of negotiations of the US-Central America Free Trade Agreement (CAFTA) to raise our concerns about the potential negative consequences of this agreement on access to essential medicines in Central American countries. MSF has good reason to believe that provisions in CAFTA related to intellectual property (IP) protection may result in needless suffering and death for our patients and millions of other people in the region with HIV/AIDS and other diseases, and undermine the historic World Trade Organization (WTO) Ministerial Declaration on the TRIPS Agreement and Public Health ("Doha Declaration").

We call upon USTR to immediately make the CAFTA text available publicly, abandon efforts to push TRIPS-plus proposals in CAFTA and other regional and bilateral trade agreements, and uphold the Doha Declaration, which the US adopted along with all other WTO members just two years ago, by explicitly supporting Central American countries in fully implementing the Doha Declaration.

SUMMARY OF CONCERNS WITH IP PROVISIONS IN CAFTA

The draft text of CAFTA has not been made public, so it is impossible to provide an informed analysis of the IP provisions proposed in the agreement. However, IP provisions in other bilateral free trade agreement (e.g. the US-Singapore agreement) are clearly TRIPS-plus, and these are consistent with proposed provisions in the Free Trade Area of the Americas (FTAA) agreement. As we have related in earlier correspondences, MSF has called upon all countries in the Americas to exclude IP provisions from the FTAA agreement altogether, as this will be the only way to *guarantee* that countries in the region can uphold the commitment they made in Doha to ensure the protection of public health and the promotion of access to medicines for all. Based on USTR's negotiating objectives in numerous bilateral and regional agreements, we feel it is safe to assume that similar provisions are proposed in CAFTA.

We have communicated our concerns about CAFTA, which, out of necessity, are based on our analysis of the draft IP Chapter of the FTAA, to you and to the FTAA Committee of Government Representatives on the Participation of Civil Society on numerous occasions over the past two years. To reiterate, MSF is concerned that the proposals would:

1. Dramatically limit the circumstances under which compulsory licenses on pharmaceuticals may be issued;
2. Extend patent terms on pharmaceuticals beyond the 20-year minimum in TRIPS;
3. Confer abusive powers to regulatory authorities to enforce patents; and
4. Grant exclusive rights over pharmaceutical data (data exclusivity).

Each of these proposals would have the effect of limiting generic competition, which has been one of the most important, reliable, and powerful forces to reduce drug prices systematically in Central America and other developing regions, making essential, life-saving medicines such as antiretrovirals (ARVs) for the treatment of HIV/AIDS more affordable for individuals and the health systems that serve them.

WHAT IS AT STAKE: THE EXAMPLE OF AIDS IN GUATEMALA

MSF currently has projects in three of the five CAFTA countries—Honduras, Guatemala, and Nicaragua—providing medical care for people living with HIV/AIDS and other sexually transmitted infections (STIs), people with Chagas' disease, displaced and homeless populations, including street children, and indigenous people. Our concerns about the effects of patents on the price and availability of essential, life-saving medicines are well known to USTR, and need not be reiterated here. However, even where there are no patent barriers, TRIPS-plus provisions will effectively delay generic competition and limit access to affordable medicines. We would like to focus particular attention on one such proposal: data exclusivity.

Although the TRIPS Agreement only requires WTO Members to protect clinical information that is generally required by drug regulatory authorities to approve the marketing of a new medicine ("undisclosed test or data") against "unfair commercial use" and "disclosure" in the framework of unfair competition law, US negotiating objectives include grant of exclusive rights on these data for at least five years. Since generic companies rely on pharmaceutical test data to demonstrate that their products are safe and effective, data exclusivity will significantly delay the introduction of generics even when there are no patent barriers.

In Guatemala, 67,000 people are living with HIV/AIDS. MSF currently provides antiretroviral (ARV) therapy for over 600 people in hospitals in Guatemala City and Coatepeque, and plans to double the number of patients on treatment next year.[1] Since ARVs are not protected by patents in Guatemala, MSF is able to use generic ARVs in its programs. Just one year ago, MSF was able to pay between 75% and 99% less for generics than the government of Guatemala paid for originator drugs. For example, the price of the ARV d4T (40mg) from Bristol-Myers Squibb was $5,271 per person per year compared with just $53 per person per year from a generic manufacturer. Although the prices of originator ARVs have fallen dramatically in the past year due to generic competition, they are still on average two to five times as expensive as quality generic equivalents, with treatment from originator companies costing on average $320-800 per month. Such a price differential still means less people receive treatment, as the average income in Guatemala is $160 per month.

In April 2003, under pressure to adopt US standards for protection of pharmaceutical test data, the Guatemalan government modified its national IP bill by passing a decree, which gives originator pharmaceutical companies five years of exclusivity on these data. This will have the effect of delaying generic competition—even where there are no patent barriers—for five years. For thousands of Guatemalans living with HIV/AIDS, five years without access to affordable ARVs can be the difference between life and death. As it stands, Guatemala is the only country in Central America that gives five years of exclusive protection for test data, but we worry that CAFTA threatens to extend such a provision to all parties to the CAFTA negotiations.[2]

[1] MSF is providing ARV treatment for 600 patients, out of a total of 1,600 Guatemalans currently receiving ARV treatment throughout the country. It is estimated that approximately 7,000 Guatemalans with HIV/AIDS are in urgent clinical need of ARV treatment.

[2] Moreover, FTAA threatens to extend data exclusivity provisions to all countries in the Americas, except Cuba.

CONCLUSION

The promise of Doha is that the TRIPS Agreement can and should be interpreted and implemented in a manner "supportive of WTO members' right to protect public health and, in particular, to promote access to medicines for all."[3] TRIPS-plus proposals in CAFTA threaten to make it impossible for countries in Central America to exercise the rights re-confirmed in Doha. As a medical humanitarian organization, we cannot accept the subordination of the health needs of our patients and millions of others to US trade interests. The US must not hamper the ability of countries in the region to fully implement the Doha Declaration, and should instead support them explicitly in doing so. In order to ensure the protection of public health and the promotion of access to medicines, the Doha Declaration must be the ceiling for CAFTA and other regional and bilateral agreements.

Sincerely,

Nicolas de Torrente
Executive Director, MSF USA

Luis Villa, MD
Head of Mission, MSF Guatemala

cc: Amb. Peter Allgeier, Deputy USTR
Amb. Ross Wilson, Senior Negotiator for the Free Trade Area of the Americas
James Mendenhall, Assistant USTR for Services, Investment, and Intellectual Property
Claude Burcky, Deputy Assistant USTR for Intellectual Property
Kira Alvarez, FTAA Intellectual Property Group
Christina Sevilla, Director for Intergovernmental Affairs
Mirta Peragio, MD, Executive Director, Pan-American Health Organization (PAHO)
Daniel Lopez Acuña, Director of Program Management, Pan-American Health Organization (PAHO)
Cesar Vieira, MD, Area Manager, Governance and Policy, Pan-American Health Organization (PAHO)

[3] See http://www.wto.org/english/thewto_e/minist_e/min01_e/mindecl_trips_e.htm