21 December 2006

Secretary of State Condoleeza Rice
U.S. Department of State
2201 C Street NW
Washington, DC 20520

Ambassador Susan Schwab
United States Trade Representative
600 17th Street, N.W.
Washington, DC 20508

Dear Secretary Rice and Ambassador Schwab:

We are writing to express our concern that the United States Department of State and the United States Trade Representative have intervened in the decision by the government of Thailand to issue a compulsory license on patents for the AIDS drug efavirenz, and to explain why the US government should refrain from such actions.

The US government is reportedly asking the Thai government to engage in prior negotiation with patent owners before issuing compulsory licenses. Not only is this not required under the World Trade Organization (WTO) rules when the compulsory license is for government use, it is not required under US law. What the WTO does require is that Thailand "promptly" notify the patent owner when it issues a compulsory license. Thailand has clearly done this. The US government should not be in the business of micro-managing Thailand's dealing with the patent owners, as long as Thailand abides by its WTO TRIPS obligations.

In 2001 the United States government and every other member of the World Trade Organization (WTO) announced the signing of the Doha Declaration on TRIPS and Public Health. This historic agreement said:

> *We agree that the TRIPS Agreement does not and should not prevent members from taking measures to protect public health. Accordingly, while reiterating our commitment to the TRIPS Agreement, we affirm that the 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.*
>
> *In this connection, we reaffirm the right of WTO members to use, to the full, the provisions in the TRIPS Agreement, which provide flexibility for this purpose.*

Thailand is obviously trying to do exactly what the Doha Declaration promised it could. Respecting Thailand's decision to exercise its right under the Doha declaration is not only a matter of concern for Thai patients in need of affordable AIDS treatment, but also a matter of good faith in honoring America's international commitments.[1]

Patient advocates and others who are concerned about the AIDS crisis have welcomed the compulsory license on efavirenz as a major step forward for access to AIDS drugs in Thailand. Thailand has stood out among developing countries for its efforts to expand treatment opportunities for AIDS patients, but the high price of newer drugs like efavirenz is a significant hurdle for the long term sustainability of AIDS treatment programs in Thailand and other developing countries.

Experts who are struggling to implement treatment programs in developing countries have concluded that it is essential to create a competitive generics market for efavirenz and other newer AIDS drugs that are patented in Brazil and other markets.[2]

Brazil did not have patents on medicines until 1996. For those AIDS drugs invented before 1996, Brazil continues to purchase generic versions. This has stimulated entry by generic manufacturers, driving the prices of active pharmaceuticals ingredients (APIs) down over time. For example, the global prices of APIs (per kilo) for lamivudine (3TC) fell from more than $25 thousand dollars in 1996 to $5 thousand by 1999, to less than $300 by 2004, illustrating the dynamic nature of cost savings from generic competition.

In contrast, the global prices for products invented after 1996, and protected by patent in Brazil, are much more expensive. This is because, contrary to popular misconception, Brazil has not issued compulsory licenses, and for AIDS drugs invented after 1996, only buys from patent owners at negotiated prices. In a 2004 study by the World Health Organization (WHO), the average API prices for six AIDS drugs purchased as generics by Brazil were $382 to $582 per kilo. For another six AIDS drugs that were patented in Brazil, the average prices for generic APIs were $1,717 to $3,020. (See table below). This illustrates the important role of economies of scale, and the global impact of decisions by large purchasers to buy (or not buy) from generic suppliers.

Thailand's decision will have important consequences, not only for Thailand, but for any developing country that needs to obtain low cost generic products. If Thailand follows through and begins to buy from generic suppliers, it will create a larger global market for generic products, stimulate competition, and lower prices everywhere for the newer products.

While the benefits of expanded generic competition are widely appreciated among experts, many developing countries have been reluctant to issue compulsory licenses because of fears that the United States government will oppose such actions and exert pressure.

We note also that the United States is itself a major purchaser of AIDS drugs in developing countries, through our contributions to PEPFAR and the Global Fund for AIDS, TB and Malaria. Thus, any action by Thailand to create more generic competition for the new AIDS drugs will benefit the US taxpayers who are shouldering the burden of these outlays.

Finally, we note that Thailand is among the countries that are supporting proposals for a treaty on R&D in the World Health Organization (WHO) new Intergovernmental Working Group on Public Health and Innovation. We agree with those who suggest this is a more appropriate way to address the US interest of sharing the global costs of medical R&D than policies that raise prices for AIDS drugs and other essential medicines.

We ask that the United States government refrain from any opposition or interference with the Thai efforts to use WTO flexibilities to buy generic AIDS medicines -- including pressuring or otherwise seeking to persuade Thailand to engage in negotiations with Merck rather than proceed to execute the compulsory license it has issued - and consider more constructive ways to promote our national interest in matters concerning innovation and access to medicines.

NOTES

[1] The USTR has publicly stated that its side letters in some Free Trade Agreements (FTAs) give countries flexibility to issue TRIPS-compliant/Doha-fulfilling compulsory licenses. Efforts by the U.S. to prevent or reverse the actual granting of such licenses raises doubts about the credibility of the United States, making it more difficult for the United States to achieve other objectives in our FTA negotiations.

[2] See the August 2006, World Bank Report, "The Economics of Effective AIDS Treatment: Evaluating Policy Options for Thailand." Page169 states "by exercising compulsory licensing to reduce the cost of second line therapy by 90 percent, the government would reduce its future budgetary obligations by US$3.2 billion discounted through 2025."

2004 Prices of Active Pharmaceutical Ingredients
Comparison of prices when products are purchased as generics in Brazil

	Lowest ($)	*Highest($)*
Products Brazil buys as generics		
Didanosine (ddI)	450	850
Indinavir (IDV)	285	400
Lamivudine (3TC)	295	480
Nevirapine (NVP)	320	475
Stavudine (d4T)	580	775
Zidovudine (AZT)	360	510
average	**$ 382**	**$ 582**
Products Brazil does not buy as generics		
Abacavir (ABC)	1,500	3,500
Efavirenz (EFV)	1,200	1,600
Lopinavir (LPV)	2,900	4,000
Nelfinavir (NFV)	900	1,400
Ritonavir (RTV)	2,600	4,320
Saquinavir (SQV)	1,200	3,300
average	**$ 1,717**	**$ 3,020**

Source: WHO, Sources and Prices of Active Pharmaceutical Ingredients, 2004.
http://www.who.int/entity/3by5/amds/en/API.pdf

Sincerely,

ACT UP East Bay, Oakland, CA

AIDS Policy Project, Philadelphia

American Jewish World Service

American Medical Student Association

Center for Health and Gender Equity (CHANGE)

Center for Policy Analysis on Trade and Health (CPATH)

Church World Service

Community HIV/AIDS Mobilization Project (CHAMP), Los Angeles, CA

Consumer Project on Technology (CPTech)

Corporate Responsibility Program, Province of St. Joseph of the Capuchin Order

Edmonds Institute

Essential Action

Global AIDS Alliance

Harm Reduction Coalition

Health Gap

International AIDS Empowerment

Maryknoll Office for Global Concerns

Middle East Children's Alliance (MECA)

Missionary Oblates of Mary Immaculate

National Action Network, Kansas Chapter

Oxfam America

Peoples' Health Movement

Progressive Intellectual Property Law Association (PIPLA)

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Association de Lutte Contre le SIDA (ALCS), Morocco

Association SunAids, Douala, Cameroon

European AIDS Treatment Group (EATG), Brussels, Belgium

Fundación Apoyo y Solidaridad, Cali, Colombia

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Latin American Network of PLWHA - RedLa+

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