Congress of the United States

House of Representatives

Washington, DC 20515

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Ambassador Randall Tobias
Global AIDS Coordinator
Office of the Global AIDS Coordinator
U.S. Department of State
SA-29, 2nd Floor, 2201 C Street, NW,
Washington, DC 20522-2920

Dear Ambassador Tobias:

Thank you for your recent testimony before the House International Relations Committee. As members who worked closely on drafting the United States Leadership Against HIV/AIDS, Tuberculosis and Malaria Act of 2003 (P.L. 108-25), legislation that created your position, we look forward to working with you to strengthen the U.S. contribution to the global fight against these killers. Specifically, we want to work with you to ensure medicines needed for the treatment of HIV/AIDS, TB, and Malaria are procured at the lowest possible cost to treat the largest number of people.

In the President's 2003 State of the Union address, he said, "Many hospitals tell [people], 'You've got AIDS - We can't help you. Go home and die.' In an age of miraculous medicines, no person should have to hear those words…Anti-retroviral drugs can extend life for many years. And the cost of those drugs has dropped from $2,000 a year to under $300 a year - which places a tremendous possibility within our grasp." Fulfilling the President's vision of extending and improving the lives of people living with HIV/AIDS in developing countries depends on the administration's support for procuring the most affordable antiretrovirals (ARVs) and other essential medicines, including fixed-dose combinations (FDCs), that meet international standards for safety, quality, and efficacy.

Over the past three years, the prices of ARVs for the treatment of HIV have plummeted from $10,000-15,000 per person per year to as little as $140 per person per year as a result of generic competition. These price reductions have allowed the U.S. government, national governments in developing countries, non-governmental organizations (NGOs), and international financing mechanisms such as the Global Fund to Fight AIDS, Tuberculosis and Malaria to deliver and fund ARV treatment, prolonging the lives of small but growing numbers of people living with HIV/AIDS in developing countries. However, these low prices continue to be available only from generic sources; brand name ARVs are on average two to five times more expensive than generic equivalents, even at drastically reduced prices.

More recently, the availability of fixed-dose combinations (FDCs) of ARVs -- pills containing two or three AIDS drugs in one tablet -- has dramatically improved the ability of treatment programs in poor countries to scale up access to ARVs and to reach people in remote settings, even in extremely impoverished rural communities. FDCs promote adherence, decrease the risk of resistance, and facilitate stock and procurement management.

Today, WHO-recommended triple FDCs are available only from generic producers because the patents of the three individual compounds are held by three different companies. The lowest available price of WHO-prequalified triple FDCs is $140 per person per year for the combination d4T/3TC/nevirapine, which is taken in the form of one pill twice a day; the lowest available price of the single products of d4T, 3TC, and nevirapine from "brand-name" producers is $562 per person per year and requires that patients take six pills per day.

In Zimbabwe, the Nobel Peace Prize-winning group Doctors Without Borders/Médecins Sans Frontières (MSF) is starting to treat patients in Bulawayo Hospital with ARVs at the cost of $244 per patient. The Centers for Disease Control and Prevention (CDC) is planning to treat 1000 patients in Zimbabwe by the end of 2005, including 400 patients at Bulawayo Hospital. Under the administration's drug procurement policy, the CDC is buying ARVs at $562 per patient. If the administration would purchase triple FDCs from generic manufacturers, rather than the individual drugs from brand-name companies, the CDC could treat more than twice as many patients.

We are concerned the administration has discredited the WHO pre-qualification standard. Evaluations carried out by the WHO pre-qualification team provide assurance that international quality standards have been applied. These standards have been developed and approved by the WHO Expert Committee system involving all WHO member states, including the U.S., and WHO governing bodies. The WHO pre-qualification project evaluates both generic and originator products. In the case of generic drugs, WHO standards for multi-source drugs are used for both dossier assessment (including bio-equivalence studies) and Good Manufacturing Practice Inspections.

WHO pre-qualification evaluations are carried out by a group of external experts providing support and expertise to a core team at WHO. The team assessing dossiers consists of representatives appointed by national drug regulatory authorities (NDRAs) from a wide range of countries including Brazil, Canada, Denmark, Estonia, Finland, France, Germany, Hungary, Indonesia, Malaysia, Philippines, Spain, South Africa, Sweden, Switzerland, Tanzania, and Zimbabwe.

Manufacturing sites are inspected by WHO experts and members of a well-established inspector network (e.g. Pharmaceutical Inspection Convention Scheme countries) and experts from countries like Canada, France, Italy, Switzerland, and the Netherlands.

The United States is isolated in its view that WHO pre-qualification standards are not sufficient to guide national drug regulatory authorities and purchasers in assessing drug quality, safety, and efficacy. The project is supported by other United Nations agencies including UNICEF,

UNAIDS, and UNFPA, as well as the Global Fund to Fight AIDS, Tuberculosis and Malaria, the Columbia University MTCT-Plus Initiative, and the World Bank. Frontline organizations that are delivering ARVs in developing countries, such as MSF, also support the WHO standards.

We are deeply concerned that the *Conference on Fixed-Dose Combination (FDC) Drug Products: Scientific and Technical Issues Related to Safety, Quality, and Effectiveness* to be held in Gaborone, Botswana, March 29-31 will not lead to the development of useful principles to be taken into account when developing and evaluating the safety, efficacy, and quality of FDCs, as stated in the draft "Scientific and Technical Principles for Fixed Dose Combination Drug Products." Rather, we believe it could undermine WHO's Prequalification Project and delay or block the use of safe, affordable generic medicines, including triple FDCs.

In light of the limited U.S. resources and the tremendous human need in the global fight against HIV/AIDS, TB, and Malaria, we urge you to accept the global standard in assessing drug quality, safety, and efficacy. The decision to purchase brand name drugs over their generic equivalent needlessly drains U.S. dollars from limited global resources and leaves thousands of HIV/AIDS patients without the medicine they need to survive.

We look forward to hearing from you regarding this matter.

Sincerely,

SHERROD BROWN
Member of Congress

BARBARA LEE
Member of Congress