



**Public comment to the International Subcommittee  
of the President's Advisory Council on HIV/AIDS:  
Implementation of the Emergency Plan for AIDS Relief**

Submitted by e-mail to [info@phnip.com](mailto:info@phnip.com), December 16, 2003  
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The following comments regarding implementation of the President's Emergency Plan for AIDS Relief (PEPFAR) are submitted on behalf of Health GAP (Global Access Project), in response to the request for public comment published December 3, 2003 in the *Federal Register* (Volume 68, Number 232). Health GAP is an advocacy organization with extensive experience campaigning nationally and internationally for increased access to affordable AIDS medicines in resource-poor settings, and the resources necessary to sustain such access.

**Summary:** The global AIDS epidemic, which will result in 100 million HIV infections by the end of this decade—despite still being in its infancy—poses an escalating threat to critical development efforts, global public health, and international security. As an emergency plan, the PEPFAR is focused on attaining the HIV prevention, treatment and care goals described in President George Bush's State of the Union Address on January 28, 2003.<sup>1</sup> However, relevant aspects of the Bush Administration's AIDS policy, overseen by the new Office of the Global AIDS Coordinator, could undermine the success of the PEPFAR. These aspects include:

- Insufficient funding levels for programs that are complementary to the PEPFAR, including the Global Fund to Fight AIDS, Tuberculosis, and Malaria (GFATM);
- The risk of wasteful duplication of bureaucratic systems and/or non-collaboration between the Bush Administration and other entities funding, advising, or implementing efforts to scale-up HIV treatment, care and prevention, such as GFATM Country Coordinating Mechanisms (CCMs) the World Health Organization's "3 by 5" emergency HIV treatment field teams, and national governments;
- Bush Administration trade policies regarding intellectual property rights (IPRs) that will increase the cost of medicines while obstructing or delaying generic competition in heavily impacted countries;
- Opposition to the procurement of generic fixed-dose combination (FDC) medicines, despite the important role FDCs play in simplifying HIV treatment, increasing adherence, and facilitating rapid treatment scale-up; and,
- Disregard for the critical clinical and ethical importance of community mobilization and the substantive involvement of people living with HIV/AIDS at every stage of program development and implementation, in order not only to overcome stigma and implement local principles of equity in community access to antiretroviral treatment (ARVs), but also to increase community uptake of ARVs and related interventions.

**The PEPFAR and the U.S. Response to Global AIDS:** The PEPFAR is a long overdue step forward by the U.S. in the fight against this pandemic, particularly in its clear integration of HIV treatment, alongside prevention and care, as an essential element of the U.S. government's response to AIDS. However, key problems posed by the Administration's AIDS policies must be

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<sup>1</sup> Pres. George W. Bush, State of the Union at the U.S. Capitol (Jan. 28, 2003).

corrected, or else the potential for the clinical success of the PEPFAR will be compromised. These comments consider key problem areas in turn, and recommend corrective action.

**1. *Insufficient funding levels for programs that are complementary to the PEPFAR, in particular the Global Fund to Fight AIDS, Tuberculosis, and Malaria (GFATM).***

UNAIDS estimates that \$10.7 billion in annual spending is needed to overcome the gap in global AIDS financing in poor countries.<sup>2</sup> This figure has already increased from the \$10 billion spending commitment for 2005 that UN countries made in 2001.<sup>3</sup> \$10.7 is the minimum required, as it represents funding only of existing infrastructure, with no money allocated for building new infrastructure or scaling up existing infrastructure.<sup>4</sup> This number will get larger: at least \$15 billion will be needed annually by 2007.

The U.S. and other donor nations' funding for global AIDS has increased significantly since 1999.<sup>5</sup> Considering the dismally low levels of funding for global AIDS that have persisted for years, recent increases are less important than the fact that funding is still falling far short of the global need, donor countries including the U.S. are breaking their commitments to fully fund the fight against global AIDS, and that U.S. funding is still far less than a proportionate share of this fight. In fact, the Bush Administration, including members of the Global AIDS Coordinator's office, advocated global AIDS funding in fiscal year 2004 at levels **lower** than the amount authorized by Congress, arguing, despite best available evidence to the contrary,<sup>6</sup> that countries could benefit from spending levels higher than what is supported by the Bush Administration.

While the Bush Administration opposed necessary global AIDS funding increases for FY 2004, existing funding mechanisms continue to be in desperate need of additional money, in particular the GFATM. The GFATM, established in 2001 as a multilateral, independent, country-driven mechanism to attract and disburse additional funding to fight AIDS, tuberculosis and malaria, has already disbursed millions in additional money to life saving programs, including HIV treatment programs.

Unlike the PEPFAR, which will require time before it can show results, the GFATM is already up and running. The PEPFAR should use existing GFATM structures, for example the national Country Coordinating Mechanisms (CCMs, which create and implement GFATM proposals). CCMs are not perfect, but they are already cultivating substantive participation and collaboration by civil society and the public sector. In order to streamline operations and decrease wasteful duplication, PEPFAR implementation should align with the work of CCMs. However, without enough money to continue to fund technically sound grant requests submitted to the GFATM, CCMs will weaken, undermining the potential for collaboration and non-duplication. Likewise, without full funding from the U.S. as well as other donors, the GFATM will be unable to support rapid scale up of HIV treatment access, resulting in more deaths, as well as diminished

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<sup>2</sup> UNAIDS, Fact Sheet, Meeting the Need (Sept. 1, 2003).

<sup>3</sup> UN General Assembly Special Session on HIV/AIDS. Declaration of Commitment on HIV/AIDS: Global Crisis—Global Action (June 27, 2001).

<sup>4</sup> Programme Coordinating Board, UNAIDS, Financial Resources for HIV/AIDS Programmes in Low- and Middle-Income Countries Over the Next Five Years (Nov. 28, 2002).

<sup>5</sup> Kaiser Family Foundation, Global Funding for HIV/AIDS in Resource Poor Settings, (December 2003).

<sup>6</sup> See Physicians for Human Rights, A Health Action AIDS Briefing Paper: Administration Claims that \$3 billion Cannot Be Effectively Used to Fight Global HIV/AIDS Are Mistaken (July 31, 2003), at <http://www.phrusa.org/campaigns/aids/briefing080403.html> Accessed November 10, 2003.

experience to pass along to the fledgling PEPFAR in implementing large-scale treatment programs.

**2. *The risk of wasteful duplication of bureaucratic systems and/or non-collaboration*** between the Bush Administration and other entities funding, advising, or implementing efforts to scale-up HIV treatment, care and prevention, such as GFATM Country Coordinating Mechanisms (CCMs) and the World Health Organization's "3 by 5" emergency HIV treatment field teams and national governments.

With 8,000 people dying daily, there is no time to waste reinventing the wheel as new bilateral and multilateral HIV programs begin HIV treatment scale-up operations. Instead of directing new financing into existing funding streams, the Bush Administration is building a new, parallel bureaucracy to award grants and accomplish monitoring and evaluation of PEPFAR-funded programs. The PEPFAR has an obligation to avoid duplication and to seek collaboration aggressively, in particular with entities like the GFATM, the WHO's "3 by 5" emergency HIV treatment field teams, as these entities are already establishing local and national systems and practices that the Global AIDS Coordinator's office should rely on in implementing PEPFAR.

Moreover, the GFATM has established a standard of transparency and conflict of interest that should be met or exceeded by the PEPFAR, including internet publication of successful and unsuccessful GFATM applications, a clear mechanism for appeals, and complete contact information for entities involved in grant application preparation and implementation.

**3. *Trade policies regarding intellectual property rights (IPRs) that will increase the cost of medicines while obstructing or delaying generic competition in poor countries.***

Patent monopolies in poor countries support high prices charged by pharmaceutical manufacturers; these high prices keep important medicines out of reach of people who need them, particularly HIV positive people dying without access to medicines. In November 2001, World Trade Organization (WTO) countries, including the U.S., agreed that countries should implement WTO rules governing the protection and enforcement of intellectual property rights in a manner that protects public health and promotes access to medicines for all.<sup>7</sup> Generic competition has had a powerful affect on drug prices, most recently reducing the cost of ARV combinations from \$10,000 to as little as \$140 per patient per year.

Despite the commitment of the U.S. to upholding the right of countries to put public health ahead of intellectual property rights protection, the Bush Administration is pursuing trade polices around the world that will delay or obstruct generic competition, increase medicine prices, and undermine the sustainable provision of HIV treatment—particularly for newer medicines that are now patent protected in most poor countries, and that will be a necessary part of second- and third-line combination treatment. Bush Administration pursuit of these trade policies has included tactics such as: inserting broader IPRs for pharmaceutical companies in emerging trade agreements to establish a Southern African Customs Union (SACU), as well as the provision of biased "technical assistance" on for heavily impacted poor countries that undermine provision of generics.<sup>8</sup>

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<sup>7</sup> WTO, Declaration on the TRIPS Agreement and Public Health (November 20 2001).

<sup>8</sup> Schroeder, Michael. *The Wall Street Journal*. Drug Patents Draw Scrutiny As Bush Makes African Visit. July 9 2003.

**4. Clinical treatment guidelines that will reject the procurement of generic fixed-dose combination (FDC) medicines, despite the important role of FDCs in simplifying HIV treatment, increasing adherence, and facilitating treatment scale-up as rapidly as possible.**

The WHO announced on World AIDS Day 2003 the prequalification of generic fixed-dose combinations (FDCs) of ARVs of assured quality.<sup>9</sup> This important development is being undermined by efforts by the U.S. to obstruct procurement by PEPFAR countries of WHO-prequalified FDCs. The simplification of treatment regimens is critical if the ambitious goals of the PEPFAR and the WHO's 3 by 5 initiative are to be attained.

The experience of national governments, NGOs, mission hospitals, and other entities currently providing ARV treatment in resource poor settings underscores the imperative of providing access to FDCs wherever possible. Through trade policy and now using questionable clinical justification, the U.S. is objecting to use of pre-qualified FDCs—medicines that are only available as a result of generic manufacturers, since brand-name companies have not permitted similar co-formulation of proprietary versions.

**5. Disregarding the critical clinical and ethical importance of community mobilization and the need for substantive involvement of people living with HIV/AIDS at every stage of program development and implementation.**

The involvement of people living with HIV/AIDS in HIV treatment scale-up efforts is necessary to overcome stigma, develop and implement local principles of equity in community access ARVs, and in order to prepare communities for the uptake of ARVs and related interventions. It is an essential clinical and programmatic element.

The importance of community mobilization and community education cannot be overemphasized in treatment scale-up efforts. Developing HIV treatment and prevention literacy, supporting voluntary counseling and testing in communities preparing for treatment scale-up, and promoting openness regarding HIV positivity improve the chances of clinical and programmatic success.

However, the PEPFAR is already applying limits to the role of community mobilization in the PEPFAR. The PEPFAR Request for Proposals regarding treatment scale up sets out an unwise 7% cap on funding community mobilization efforts.<sup>10</sup> This cap should be removed, and the Bush Administration should develop a working strategy for maximizing community mobilization as a way to increase the likelihood of ARV treatment scale-up success.

**Recommendations for the Global AIDS Coordinator and the Bush Administration:**

- Increase the size of its global AIDS funding and the pace of its disbursement proportionate with global need and U.S. wealth, to a **minimum** of \$5.4 billion in 2005, with cumulative investments of \$30 billion between 2004 and 2008. Substantial portions of this investment must be directed to the GFATM as a mechanism that is already operational, accountable, transparent, effective, and capable of absorbing and disbursing large amounts of funding.

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<sup>9</sup> Associated Press. WHO Certifies New Generic HIV Drug. December 1, 2003.

<sup>10</sup> See Centers for Disease Control Request for Proposals. Rapid Expansion of Antiretroviral Therapy Programs for HIV-Infected Persons in Selected Countries in Africa and the Caribbean Under the President's Emergency Plan for AIDS Relief." At [www.cdc.gov/od/pgo/funding/04080.htm](http://www.cdc.gov/od/pgo/funding/04080.htm) Accessed November 10, 2003.

- Actively collaborate with the GFATM and other stakeholders, building on existing mechanisms such as GFATM CCMs to avoid wasteful duplication of efforts, increase collaboration, and minimize bureaucracy and overhead.
- End efforts, through bilateral and regional trade deals, as well as through trade pressures and biased technical assistance provided to national governments by USAID and other agencies, to extract standards for protection and enforcement of IPRs that exceed the standard set out by the WTO.
- Support the efforts by the WHO for prequalification of quality generic FDCs in order to maximize treatment coverage, simplify treatment regimens, and improve compliance. Permit procurement of generic FDCs with PEPFAR money.
- Prioritize the substantive involvement of people living with HIV/AIDS who have experience in community mobilization and efforts to increase the HIV treatment literacy at every stage of program design, implementation, and monitoring. Incorporate community mobilization into PEPFAR implementation efforts by removing the 7% cap on financing for community mobilization financing currently set by the relevant Request for Proposals. People living with HIV/AIDS should be permitted to select their own representatives among the stakeholders who coordinate with U.S. Department of State officials in the field in PEPFAR countries in the development of strategic PEPFAR plans.