



U.S. Emergency Plan for AIDS Relief (PEPFAR): Facts and Critical Issues

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On February 23, 2004, the Bush administration unveiled its five year global AIDS plan, including the first round of grantees for its Emergency Plan for AIDS Relief (PEPFAR). Below are facts about the U.S. program and critical policy issues that are causing AIDS treatment access activists grave concern.

Facts about PEPFAR:

The PEPFAR is a bilateral AIDS program that is part of a 5 year, \$15 billion initiative to combat AIDS in 14 African and Caribbean countries.

On February 23, 2004, the Bush administration released a “strategic plan” to fight global AIDS, and announced the first round of grants totaling \$350 million for care, treatment, and prevention programs..

Ambassador Randall Tobias, a former CEO of the drug company Eli Lilly, is the coordinator of the U.S. Global AIDS Initiative (GAI), which coordinates all U.S. global AIDS efforts across U.S. relevant agencies.

PEPFAR FUNDING:

Although its funding level will be decided upon on an annual basis, the Global AIDS Initiative is authorized to receive \$15 billion over 5 years

* \$9 billion in new funding on the 15 PEPFAR focus countries broken out by programs

- 55% for treatment programs
- 20% earmarked for prevention (one third for abstinence-only programs)
- 15% for palliative care
- 10% for orphans and vulnerable children
- \$1 billion over 5 years to the Global Fund
- \$5 billion to ongoing bilateral HIV/AIDS programs

The U.S. blocks generics, including fixed-dose combinations

The use of three-in-one drug combinations is critical if the ambitious goals of the PEPFAR and the WHO’s “3 by 5” initiative are to be met. The WHO, World Bank, Global Fund to Fight AIDS, Tuberculosis and Malaria, UNICEF and current AIDS treatment providers, such as MSF, support the use of generic fixed-dose combinations of antiretrovirals to increase patient adherence, reduce costs, and increase the simplification of treatment. In attempt to undermine World Health Organization (WHO) standards for drug quality and safety, the Administration plans to host a meeting at the end of March on the safety and quality of generic 3-in-1 antiretroviral drug combination medicines. These fixed-dose combinations (FDCs) of antiretrovirals are efficacious and preferred over any single pill regimen because their ease of use helps to increase adherence and lower cost facilitates treatment scale-up (repeating what is said above). Brand-name companies have not permitted similar co-formulation of their proprietary medicines.

The World Health Organization has prequalified three generic versions of FDCs, meaning they have assured the quality of a given manufacturer’s product. The WHO’s standards for pre qualification are endorsed by UNICEF, the World Bank, the Global Fund to Fight AIDS, TB, and

PEPFAR GOALS:

- Prevent 7 million new HIV infections by 2008
- Provide anti-retroviral therapy to 2 million individuals
- Provide care to 10 million people infected and affected by HIV/AIDS, including orphans and vulnerable children through 2008

FOCUS COUNTRIES

Botswana, Ivory Coast, Ethiopia, Kenya, Mozambique, Namibia, Nigeria, Rwanda, South Africa, Tanzania, Uganda and Zambia, as well as Guyana and Haiti in the Caribbean. According to the PEPFAR strategy document, these 14 countries represent 50% of all HIV infections in the world and 70% of all HIV infections in Africa and the Caribbean. A 15th focus country outside Africa or the Caribbean, has yet to be named.

Money for Treatment: First PEPFAR Round

The first PEPFAR grant awards for scaling up ARV treatment were made to the following institutions and/or consortia:

Catholic Relief Services:

- Funding amount: \$335 million over five years, \$24.7 million in year one
- Countries: South Africa, Zambia, Nigeria, Kenya, Rwanda, Uganda, Tanzania, Haiti and Guyana

Columbia University Mailman School of Public Health/MTCT-Plus Initiative Multicountry Columbia Antiretroviral Program (MCAP):

- Funding amount: \$125 million over five years (unclear what first year grant award is)
- Countries: Kenya, Mozambique, Rwanda, South Africa, and Tanzania

Harvard AIDS Institute, Harvard School of Public Health:

- Funding amount: \$107 million over five years, \$17 million year one
- Countries: Nigeria, Botswana, and Tanzania

Elizabeth Glaser Pediatric AIDS Foundation:

- Funding amount: Not published on EGPAF website
- Countries: Côte d'Ivoire, South Africa, Tanzania and Zambia

Malaria, Columbia University's MTCT-Plus program, international humanitarian organizations such as Médecins Sans Frontières (MSF), national governments, and other programs with experience treating people living with HIV.

If Bush is successful in blocking the procurement of generic FDCs, this will result in approximately two to four times fewer people on life-saving treatment than would gain access using more affordable generic equivalents. The best world price for WHO's recommend first line of treatment (d4T/3TC/NVP) from originator companies is US\$562 per person per year (in the form of 6 pills a day) compared with the generic equivalent 3 in one pills taken twice a day which costs as little as \$138-\$270 per person per year.

The U.S. is imposing a new barrier to access to quality generics and the entry of generic products to the global market, namely unnecessary quality standards. The U.S. is disregarding international quality standards set by the World Health Organization in its pre-qualification project and plans to impose a parallel and competitive option of standards they know are unattainable for generic producers. In this way the U.S. plans to shut out WHO pre-qualified generic producers.

Note: The U.S. is sponsoring a meeting with "stakeholders" on these issues: "Conference on Fixed-Dose Combination (FDC) Drug Products: Scientific and Technical Issues related to Safety, Quality, and Effectiveness," 29-30 March 2004 in Gaborone, Botswana. For more information, email info@healthgap.org

WHO on the benefits of FDC's:

- Increase patient adherence to treatment (especially FDCs)
- Delay the development of resistance (especially FDCs)
- Lower the total cost, including production, storage, transport, dispensing, and other health system costs
- Reduce the risk of medication errors by prescribers, dispensers, or patients themselves
- Simplify and increase security of supply systems (especially FDCs)
- Facilitate patient counseling and education, reduce waiting time
- Help in scaling up access to ARVs as their use has been associated with significant increase in enrollment in some pilot ARV programmes.

–From "Fixed dose combinations for HIV/AIDS, Tuberculosis, and Malaria: Current status and future challenges from clinical, regulatory, intellectual property, and production perspectives," WHO hosted meeting in Geneva, 16-18 December 2003.

CRITICAL ISSUES

1) DEATH & DELAY

More than 3 million people died of HIV/AIDS between the time Bush announced the U.S. Presidential Emergency Plan for AIDS Relief (PEPFAR) initiative in January 2003 and February 23 2004 when the five year strategic plan was unveiled along with the first round of grants totaling \$350 million for care, treatment, and prevention programs throughout some of the 14 Africa and Caribbean “focus countries.” Activists are critical of the administration for creating a bilateral initiative requiring a new bureaucracy while underfunding the cash-strapped Global Fund to Fight AIDS, Tuberculosis, and Malaria. The Global Fund has been providing financing to poor countries for programs since its launch in January 2002.

2) GO-IT-ALONE STRATEGY

The Bush plan undermines would-be complementary programs by not collaborating with the 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. Under the premise of concern about “high quality” of medicines the U.S. is also seeking to undermine WHO-sanctioned standards on treatment protocols and quality requirements for medicines to route PEPFAR funds to name-brand pharmaceutical companies.

3) INSUFFICIENT FUNDING

Donor countries, including the U.S., should contribute to the global fight against AIDS as a proportion according to their wealth. The U.S. GDP is 33% of the global economy and should therefore be responsible for at least one-third of the costs. The \$15 billion program, spread out over 5 years, is still only half of the US’s “fair share” of what UN experts estimate to be the cost of HIV/AIDS programs by 2008. U.S. annual commitments lag behind even further: Bush has budgeted \$2.8 billion for 2005 on global AIDS although the U.S. fair share of \$15.3 billion needed is at least \$5.4 billion.

4) UNDERFUNDED (and UNDERMINED) INTERNATIONAL ACTIONS

The Global Fund remains the most effective and efficient financing vehicle to address this world health disaster but is continually underfunded by donors. Bush’s global AIDS plan sets aside only \$1 billion over a 5 year period for the Global Fund and has tried setting a cap for annual contributions for \$200 million--which for 2005 represents a 64% reduction in funding from the previous year.

The World Health Organization (WHO) “3 by 5” initiative must receive financing and support but has been neglected by all donor countries. For WHO to provide the necessary technical assistance for national ARV programs and GFATM applications, donor countries need to contribute at least \$350 million in 2005. The U.S. strategy plan barely mentions “3 by 5” and does not provide any financing.

5) COORDINATION AT THE NATIONAL LEVEL WITH PUBLIC SECTOR

Donor-financed programs should bolster public health systems towards the goal of universal access to HIV/AIDS treatment operated by national governments and accountable to communities living with HIV/AIDS. However, the first round of PEPFAR grants favor international NGOs, US government agencies, and U.S. universities as the prime recipients and implementers of AIDS programs. These grantees are under no obligation to coordinate with national bodies, such as national government, CCM’s and NAC’s, or to integrate their vertical intervention-specific programs with public health systems, or implement programs in accordance with WHO guidelines for resource-poor settings.

6) AFFORDABILITY and SUSTAINABILITY

The U.S. must make the affordability of HIV/AIDS treatment the highest priority in order to ensure long-term sustainability & maximum coverage. However, the plan is posed to waste money on brand name drugs in order to benefit the powerful U.S. drug company lobby. Also, PEPFAR does not require grantees to provide HIV/AIDS treatment for free, a necessary provision to help with adherence.

7) AFFORDABLE GENERIC DRUGS

In a section on drug procurement, the PEPFAR strategy paper lauds concessionary efforts by brand-name drug company, such as discounts, differential pricing, and donation programs, that have been criticized internationally as unsustainable half-measures. Also, the plan does not recognize the importance of generic competition in keeping drug prices affordable.

While Ambassador Tobias and U.S. officials have given lip-service to buying generics, the government, working with the U.S. pharmaceutical lobby, is expected to require poor countries to purchase brand name AIDS drugs with PEPFAR funding, rather than cheaper generic antiretrovirals. If the plan was to operate under the same principles of the Global Fund, to seek out and support the purchase of the most affordable medicines pre-qualified by the WHO, it would mean more people on treatment with less money, a larger market for generic producers which in turn drive prices even lower, and less unnecessary costs to subsidize what is already the world's most profitable industry--the research-based pharmaceutical industry.

8) COMMUNITY INVOLVEMENT & TREATMENT PREPAREDNESS

The U.S. disregards 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), and deliver treatment education, but also to increase community uptake of ARVs and related interventions. By requiring \$1 million minimum for grant requests and circumventing national bodies and consortia of NGOs, community-based organizations are being shut out of PEPFAR funding and programs.

9) PREVENTION, NOT POLITICS

In light of studies highlighting the vulnerability of married women and the need for effective prevention strategies, the U.S. must support science-based interventions, rather than dictate unscientific approaches such as abstinence- only interventions. The

mandate to spend one-third of prevention monies on abstinence-only programs undermines the importance for community best practices and locally driven strategies.

10) WOMEN, MARGINALIZED GROUPS, AND EQUITY

It's unclear how the U.S. will support vulnerable and marginalized groups rather than perpetrating a two-tier system of the "haves" and "have nots" based on social issues. The U.S. must support policies that reduce the vulnerability of women and girls to infection and needless death, including greater access to female condoms; HIV, STD and reproductive health services; and programs preventing maternal-to-child transmission while ensuring treatment for mothers and families.

Intellectual Property Rights and PEPFAR

Bush's trade agenda has focused on increasing patent rights for drug companies, even in poor countries, where patent monopolies result in higher cost and decreased access. The emerging free trade agreement between the U.S. and the Southern African Customs Union, for example, would inhibit access to low cost generic versions of important patented medicines. In Nigeria and Uganda the U.S. has pressured local officials to enact national patent policies that exceed the strict rules of the WTO and would restrict countries' rights to break patent monopolies to reduce medicines cost. The PEPFAR strategy paper paves the way for more this pressure through "technical assistance in policy development," including "treatment-related policy issues" and "TRIPS and other trade agreements." Also, the paper reflects Big Pharma's position that innovation and drug pipeline are threatened unless intellectual property rights are stringently upheld.

FOR MORE INFORMATION

Health GAP (Global Access Project)

www.healthgap.org

Medicins sans Frontiers (MSF)

www.accessmed-msf.org

U.S. Office of the Global AIDS Coordinator

www.state.gov/s/gac/

World Health Organization (WHO)

www.who.int