CSIS HIV/AIDS TASK FORCE

Advancing U.S. Leadership on Global HIV/AIDS

Opportunities in the PEPFAR Reauthorization Process

A Report of the Task Force on HIV/AIDS
Center for Strategic and International Studies

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Advancing U.S. Leadership on Global HIV/AIDS

Opportunities in the PEPFAR Reauthorization Process

J. Stephen Morrison, Allen Moore, and Jennifer Cooke [1]

The President's Emergency Program for AIDS Relief (PEPFAR) was unveiled in 2003, just four years ago, in the middle of the first Bush administration. Follow-on events moved rapidly. Congressional support was mobilized, legislation enacted, appropriations provided, leadership and staff set in place, and implementation activities begun. Thus began the United States' largest mobilization ever to combat a single disease.

PEPFAR's first five-year phase will come to an end in 2008, and congressional reauthorization of the program will begin in 2007. For symbolic, diplomatic, and operational reasons, it will be vital that the transition to the initiative's follow-on phase be effected seamlessly, without major disruptions to key programs now in place and without generating major or protracted uncertainties among recipient countries and other donors. For this reason, Congress and the administration should begin now to forge a strategic vision of PEPFAR's future trajectory, to examine how best to build on PEPFAR's many achievements to date, and to tackle some of the pressing challenges that have arisen in the program's initial phase.

A congressionally mandated study of PEPFAR implementation completed by the Institute of Medicine (IOM) in March 2007 concluded that the program's most important early accomplishment has been "to demonstrate that HIV/AIDS services, particularly treatment, can be rapidly scaled up in resource-

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constrained…countries—something that many had doubted could be done."[2] The law authorizing PEPFAR, *United States Leadership against HIV/AIDS, Tuberculosis and Malaria Act of 2003*, PL 108-25, will expire on September 30, 2008, marking the end of PEPFAR's initial promising five-year phase.

It is anticipated that total U.S. expenditures on global HIV/AIDS from 2004, when PEPFAR was launched, through 2008 will total nearly $18 billion.[3] It is estimated that aggregate annual global spending on HIV/AIDS in the developing world from all sources will have risen from $1.6 billion in 2001 to $8.3 billion in 2004 to over $10 billion in 2008.[4]

- As of early 2007, U.S. programs have contributed to over 850,000 persons receiving life-sustaining antiretroviral treatment. The World Health Organization (WHO) estimates that antiretroviral therapy coverage in the developing world has increased four-fold since 2003, today reaching 1.6 million people or 24 percent of those in need.[5] That number is projected to grow by 50,000 persons per month through the end of fiscal year 2008.
- As of early 2007, the United States has provided 61.5 million persons with community outreach activities to prevent sexual transmission of HIV and supported antiretroviral prophylaxis for HIV-positive women during 533,700 pregnancies, averting an estimated 101,500 infant HIV infections.[6]
- As of 2007, the United States gives direct or indirect support to 2 million orphans and vulnerable children and provides direct or indirect care to more than 2.4 million people living with HIV/AIDS.[7]

Notwithstanding the unprecedented commitment of resources by the United States, other donors, and affected countries, approximately 5 million additional persons continue to become infected by HIV each year, and an estimated 3 million die annually of AIDS. As the leader of, and largest donor to, the global HIV/AIDS response, the United States holds a special power and opportunity to help actively chart the best global responses to HIV/AIDS into the future.

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[2] IOM Committee for the Evaluation of PEPFAR Implementation, *PEPFAR Implementation: Progress and Promise* (Washington, D.C.: National Academies Press, March 2007), p. 4.
[3] See Office of the U.S. Global AIDS Coordinator (OGAC), "PEPFAR Overview Fact Sheet," February 2007, http://www.pepfar.gov/press/81352.htm.
[4] See Jennifer Kates and Eric Lief, *International Assistance for HIV/AIDS in the Developing World: Taking Stock of the G8, Other Donor Governments and the European Commission* (Washington, D.C.: Kaiser Family Foundation, July 2006), p. 2 and accompanying chartpack, http://www.kff.org/hivaids/7344.cfm.
[5] WHO and UNAIDS, "Fact Sheet: Progress in Scaling up Access to HIV Treatment," July 2006, http://www.who.int/hiv/toronto2006/FS_Treatment_en.pdf.
[6] OGAC, "PEPFAR Overview Fact Sheet."
[7] For definitions of direct and indirect care, see chapter 3, "Critical Intervention in the Focus Countries: Care," *The Power of Partnerships: Third Annual Report to Congress on PEPFAR* (Washington, D.C.: Office of the U.S. Global AIDS Coordinator, 2007), http://www.pepfar.gov/press/c21604.htm.

An Appeal for a Renewed Vision

The White House and Congress should give priority to advancing a compelling, informed, and expanded vision for the next phase of PEPFAR and the U.S. response to global HIV/AIDS. U.S. national interests argue strongly for such action. Timing is important because recipient countries are being pushed to make major investments in their own health sectors, and they both require and deserve the assurance that international resources will continue to be available to help them to meet shared objectives. Other donors also need assurance that the United States will continue its financial leadership, if they are to step up their own contributions to global HIV/AIDS control efforts. Finally, implementing partners in countries acutely affected by HIV/AIDS need assurance that they can continue to build capacity according to multiyear plans based on reliable future funding flows.

An expanded vision for the future of PEPFAR needs to reflect all that has changed in recent years.

The moral, political, economic, and security stakes associated with the global HIV/AIDS pandemic have steadily increased. Moral obligations to those whose lives are sustained through U.S. action have become a durable feature of U.S. foreign policy. As instruments of U.S. global soft power become ever more important, PEPFAR provides a source of goodwill by helping to stabilize disease-shattered economies and by reducing the security threats that typically accompany economic and political instability. Further, it is a domestic issue around which genuine bipartisan consensus can be reached.

For all the good that PEPFAR has generated, programmatic and operational challenges on the ground continue to demand adjustments in the U.S. approach and underline the critical need for ongoing applied research. Knowledge of what approach is most effective in confronting the pandemic is developing rapidly, and that knowledge must be applied aggressively and consistently in the field. The growing body of knowledge on how to improve global cooperation in the international response also must be consistently applied.

In sum, the first three and a half years of PEPFAR have been a period of relative success in winning rapid, substantial gains. There is enthusiasm and momentum, both in the field and among policymakers at home. The United States is positioned to build on that momentum, early and systematically, to assure continuing progress. The time to move forward is 2007.

Future success is not a foregone conclusion. Rising budgetary needs for HIV/AIDS come into direct conflict with growing pressures to constrain budget growth across all sectors of the U.S. government. Budget pressures also arise from the fact that the U.S. currently provides about half the funds donated by all nations for HIV/AIDS, a proportion that is not sustainable. Even as budget constraints threaten the continued rapid expansion of PEPFAR, there is growing concern in Congress and among advocates that traditional global health programs—maternal and child health, family planning, and infectious disease—

are declining in real terms, potentially undermining the positive impact of PEPFAR.

There are also serious policy and operational challenges that have emanated from PEPFAR implementation that require careful, systematic attention. If unattended, or mismanaged, the controversies and challenges that have surfaced in PEPFAR's initial phase could undermine both domestic and international enthusiasm for the continued expansion of U.S. leadership on global HIV/AIDS and related diseases.

The Legacy of PEPFAR's Initial Phase: 2003 to 2007

In combination, PEPFAR; the Global Fund to Fight AIDS, TB, and Malaria; public and private donor contributions; and aggressive action by affected countries have created a new legacy of commitment, knowledge, and experience. This legacy will play a critical role in the development of future choices about U.S. leadership on HIV/AIDS.

Notwithstanding ongoing problems and challenges, PEPFAR's five-year record has affirmed universal values, extended the lives of millions of persons, brought honor and respect to the United States, and helped stabilize poor countries under threat.

As the IOM review makes clear, PEPFAR has played a critical international role in helping to demonstrate that:

- Antiretroviral treatment on a mass scale is both affordable and logistically achievable.
- Prevention of HIV transmission has to be an integral part of current and future HIV/AIDS strategies. Behavior change is possible and can reduce new infections.
- Worthy, effective, and committed partners, both governmental and nongovernmental, exist in the most heavily affected countries and can be strengthened in demonstrable ways.
- There is early evidence that U.S. programs can be successfully harmonized with the activities of affected countries, international organizations, and other donors.
- New institutional arrangements within the U.S. government, including the directional guidance of the Office of the U.S. Global AIDS Coordinator and the elevated authority of embassy teams, can channel diverse agencies toward common ends.
- Bipartisan support continues in Congress for increasing HIV/AIDS spending, as demonstrated most vividly in the February 2007 decision to increase appropriations for HIV/AIDS in the current fiscal year.
- Success with a disease-specific, country-focused initiative has opened the way for the President's Malaria Initiative and potentially for other future broadening health efforts.

- Global health has been established as a central facet of U.S. foreign policy. HIV/AIDS and other emerging infectious diseases are now understood to be transnational security threats, in a period when U.S. national interests in Africa have risen steadily.
- U.S. health diplomacy has been elevated and strengthened and has achieved multiple concrete, results. U.S. leadership has contributed directly to the formation of new international initiatives like the Global Fund; challenged other donors to expand their investment in HIV/AIDS; and led to the creation of numerous new public-private partnerships in global AIDS response. U.S. dialogue with China, India, and Russia has advanced, focusing on collaborations that may leverage the impressive capacities of these major powers on global health matters.
- U.S. public support for contributions to global health has increased. U.S. investments have contributed to expanded advocacy coalitions comprising traditional development advocates, nongovernmental organizations (NGOs), schools of public health newly engaged operationally in expanding their programs, faith-based organizations, and U.S.-based foundations seeking to have new strategic impact on global health and developmental outcomes. Recent surveys confirm high U.S. public support for even larger U.S. funding response and leadership commitments in addressing the global epidemic.[8]

In retrospect, the unprecedented expansion of U.S. investment in global HIV/AIDS has become a highly effective instrument of "soft power," facilitating global health's graduation into the mainstream of U.S. foreign policy and creating a new momentum. In today's post-9/11 world, these are standout achievements. They provide a platform on which the multiple gains achieved thus far can be enlarged.

The two key challenges at this juncture are to make certain that high-level U.S. political engagement persists and that U.S. investments become reliably sustainable over time.

The Core Challenge of Sustainability

Progress generates new demands. It also generates, inexorably, new uncertainties, tensions, and controversies. Sustainability of U.S. leadership over the long term requires consciously addressing these factors:

Political Leadership. PEPFAR has been driven by the White House, with a significant level of involvement by the president himself. Congress has supported him on a bipartisan basis. Any large foreign assistance initiative requires a high-profile commitment by the White House, and it is therefore essential that a foundation be laid now for the next president to carry forward and build on existing gains.

[8] See Kaiser Family Foundation, "Public Opinion on the Global HIV/AIDS Epidemic," *Kaiser Public Opinion Spotlight* (August 2006), http://www.kff.org/spotlight/hivglobal/index.cfm.

Financial Resources. Experts estimate current global needs for HIV/AIDS at $18 billion, 80 percent more than the current $10-billion global investment. In part because the spread of HIV has not yet begun to slow, global need is growing faster than global investment, and a way must be found for donors and investment partners alike to close this gap.

Health System Deficits. One of the greatest challenges on the ground is to build out the capacity of national health systems to meet both the new demands of an HIV/AIDS response and the traditional health needs of developing countries, including pressing needs such as child survival, maternal health, family planning, and other infectious diseases such as TB and malaria. All relevant institutions must be included in an expanded partnership, including governments, donors, NGOs, faith-based organizations, corporations, and health professionals. Spending for HIV/AIDS must not have the unintended consequence of weakening traditional systems by diverting scarce personnel and resources. Along with financing deficits and physical infrastructure deficits, workforce deficits must be overcome if global health is to be improved.

HIV Prevention. Ideological arguments over HIV-prevention techniques and technologies have proved to be one of the most divisive issues surrounding U.S. participation in the global AIDS response. Compromise and cooperation are essential to overcoming these divisions and to creating a new consensus that has the promise of greater stability and sustainability. The prevention imperatives are especially acute for women and girls and highlight the need for better field evidence to guide programs and for closer linkage of HIV-prevention programs to other developmental initiatives, including education for girls, legal reform, access to economic resources, and campaigns to reduce violence against women. A more realistic approach to the highly efficient transmission of HIV through injection drug use will also be essential to future effectiveness of prevention efforts.

Issues for PEPFAR Reauthorization

In the process of reauthorization of PEPFAR, Congress will need to grapple with a number of critical questions, both at the strategic level and at the programmatic and operational level.

Strategic Considerations

At the strategic level, authorizers will need to consider how the objectives and scope of the initiative might change and how the program fits within the evolving context of global health and development assistance. PEPFAR was conceived as an emergency response, with priority emphasis on getting resources to the field quickly and providing antiretroviral treatment to those in need. Today, HIV/AIDS remains an urgent global problem, but there is growing recognition that the United States will need to broaden its approach to one that responds with the urgency required, but one that also lays more fully the foundation of a long-term, sustainable health and development commitment.

Strategic questions for this expanded vision of PEPFAR will include consideration of the broad parameters and overall objectives of the initiative.

- How should PEPFAR's objectives shift in its second phase? Congress should consider whether overall numerical targets—for individuals reached by treatment, care, and prevention services—remain adequate benchmarks for PEPFAR success or whether additional health systems and sustainability benchmarks should be formally incorporated into the program's objectives.
- Congress will need to consider the broader balance between HIV interventions and other related development and health priorities—TB and malaria control, nutrition, maternal health, family planning, child survival—and how HIV and other health interventions can be better integrated. Similarly, it will need to examine how much emphasis should be placed on the long-term strengthening of health systems—improved infrastructure, increased heath and community workforce capacity, for example—versus interventions specific to HIV/AIDS.
- "New" program objectives may require new authorization levels, and these authorization levels will need to be weighed against funding for other programs, for example the Global Fund, and with other programmatic, research, and development priorities.
- Congress may wish to consider a move away from the "focus" country approach to broaden country eligibility for funding. Focus country programs that have achieved national treatment scale-up, for example, could be "graduated" to a different program model. Or, the program could shift to a negotiated compact model that defines respective obligations and performance benchmarks of partner governments. The reauthorization should also address how best to fit the "next wave" countries—India, China, and Russia—into the overall U.S. approach.

Programmatic Considerations

Reauthorization negotiations will offer an opportunity to incorporate valuable lessons learned at the programmatic level from the first four years of implementation and to systematically debate and address some of the more controversial aspects of the initial PEPFAR legislation.

- *Country ownership.* As the reauthorization process gets underway, it will important to incorporate perspectives from those states most acutely affected by HIV and to persistently assess whether PEPFAR program administration is adequately aligned with the priorities and needs of recipient countries. This is also an opportunity for the United States to consider how best it can genuinely coordinate its efforts with those of other donors and key stakeholders.
- *Prevention.* PEPFAR has dramatically demonstrated the possibilities of expanded access to treatment in the developing world. But there is today growing acknowledgement of the centrality of HIV prevention to program

sustainability and ultimately to stemming the spread of HIV. Congress will need to examine how best to elevate and evaluate prevention efforts within the PEPFAR initiative. It might consider moving to "outcome" rather than "process" targets in prevention—for example, aiming to bring national HIV incidence or prevalence in a given country below a target percentage. It should also consider appropriate allowances in the legislation for the introduction and implementation of new intervention technologies and methods—for example, male circumcision and pre-exposure prophylaxis.

- *Earmarks.* Funding earmarks for treatment, for orphans and vulnerable children, for blood safety, and for abstinence-until-marriage interventions have been a source of some debate, constraining implementers, according to some observers, from responding adequately to host-country priorities. The IOM study recommends replacing the earmarks with a more flexible structure. Congress will need to debate whether such a shift should be included in PEPFAR reauthorization and, if they are preserved, whether new earmarks should be considered for women and children, health care workers, and other potential priority sectors.
- *Gender.* Congress will need to consider how to more effectively address the acute vulnerabilities of women and girls. There are already, for example, promising models of integration of reproductive health and HIV/AIDS services that expand the reach of HIV services to women and girls and make optimal use of scarce resources. Innovative and successful "wraparound" programs that address the nexus between HIV/AIDS and women's social, economic, and legal empowerment may warrant additional support.

  In some cases, strengthening gender provisions will require working through and finding common ground on some of the more ideologically divisive issues in HIV-control efforts. The antiprostitution pledge, for example has been criticized on public health grounds as potentially excluding key partners who are able to reach vulnerable and high-risk populations. Some observers argue that the current legislation's language on abstinence interferes with the best use of limited prevention funds, given that in many countries married women are among those groups most at risk. These debates will need to be approached with sensitivity and respect and with clear and reliable understanding of the public health costs and benefits associated with different approaches.
- *Treatment.* As antiretroviral treatment programs expand, the United States and the international community will need to continue to meet the critical need for rapid and safe drug approvals, which may require strengthened coordination between the WHO drug-approval process and the Food and Drug Administration fast-track process. Over time, an increasing number of individuals will need to shift from first-line antiretroviral therapy to far more expensive second-line regimens. The United States and other donor

countries will need to prepare now for dramatic increases in the cost and complexity of treatment programs.

- *Research and evaluation.* Congress should seek to strengthen operational research as an integral part of PEPFAR implementation. Reliable data and analysis on the direct and ancillary impacts of PEPFAR programs will be essential to crafting an effective long-term U.S. and global response to HIV/AIDS, and the gathering of such data and research should be given adequate priority. Congress should also seek to institutionalize the Institute of Medicine's independent, external review process as PEPFAR moves into its second phase.

Congress has an opportunity to preserve and build on PEPFAR's achievements to date and incorporate the many valuable lessons learned in the program's initial phase. The reauthorization process has the potential to become contentious, but it could also continue to be a model of bipartisan cooperation to address a historic global threat. It is also an opportunity to strengthen the spirit of partnership with those countries most affected, and congressional authorizers should strongly consider soliciting opinion and advice directly from leaders, governmental and otherwise, in those countries they are seeking to assist.

The White House and Congress are urged to move forward aggressively on PEPFAR reauthorization beginning in 2007. The future of nations and tens of millions of lives hang in the balance.