



**U.S. Strategy for
Rapid Scale-Up of
ARV Treatment:
Advocacy Issues
and Concerns**

December 2003

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Design: Manu Badlani

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U.S. Strategy for Rapid Scale-Up of ARV Treatment: Advocacy Issues and Concerns

Policy Background and Report from a Consultation

Landmark legislation approved in 2003 expanding the U.S. response to the global AIDS crisis requires the President to establish a comprehensive, integrated, five-year strategy “that strengthens the capacity of the United States to be an effective leader of the international campaign against HIV/AIDS.”¹ The government-wide strategy is intended to guide policies and programs to meet specific targets for prevention, treatment, and care and support.

A consultation on “U.S. Strategy for Rapid Scale-Up of ARV Treatment: Advocacy Issues and Concerns” was held in December 2004 to provide an opportunity for global AIDS advocates, including representatives of operational, research, and policy organizations, to reflect on the policies needed to meet the legally mandated goal for expanding access to antiretroviral

(ARV) treatment. The consultation included an examination of lessons gleaned to date from current ARV treatment programs, an overview of the World Health Organization’s treatment initiative, dialogue with selected policymakers, and deliberations to identify strategic priorities for advocacy.

This report first provides background on international developments concerning ARV drugs, and on U.S. policy on the issue. Next, it summarizes the presentations by a panel of representatives from organizations that are providing ARV treatment in developing countries, and another presentation on the World Health Organization’s “3 by 5” Campaign. Finally, it outlines the key elements identified by consultation participants as essential for successful scale-up of ARV treatment.

¹ Public Law 108-25

I. The Treatment Imperative

“The time has come to put all the pieces together. Plans have been made. Needs are clear. Solutions are available. Leadership is gathering momentum. Now act!”

—Dr. Peter Piot
Executive Director, UNAIDS
Report on the Global HIV/AIDS Epidemic,
2002

The past three years have witnessed a turning point in the global response to the HIV/AIDS epidemic. Since 2001, world leaders have committed themselves to achieving concrete objectives by specific deadlines, prices for ARV drugs have been dramatically reduced, and a new global institution to mobilize and disburse additional resources – the Global Fund to Fight AIDS, Tuberculosis, and Malaria (GFATM) – has been established.

This more robust global response to HIV/AIDS was prompted, in part, by the unforeseen magnitude of the epidemic. UNAIDS reported in July 2002 that “The scale of the AIDS crisis now outstrips even the worst-case scenarios of a decade ago.”² That report found that an estimated 40 million adults and children in developing countries were living with HIV/AIDS and the rate of infection was continuing to increase, even in high prevalence countries. In Zimbabwe, for example, HIV prevalence among pregnant women climbed from 29 percent in 1997 to 35 percent in 2000.

For a number of years the policy debate was over allocating resources to prevention *or* treatment. The consensus that emerged and is now widely accepted is that prevention and treatment are both part of a continuum of care and that the availability of treatment can reinforce prevention efforts.

Currently six million of the 40 million people living with HIV/AIDS in developing countries need ARV

therapy. Without access to ARVs, virtually all of those six million will die before 2005.³ By December 2002, only 300,000 people in resource-limited settings had access to these life-saving medicines, with fully half of those living in Brazil. In sub-Saharan Africa, only 50,000 out of the 4.1 million in need received ARV therapy in 2002.

“The AIDS treatment gap is a global public health emergency. We must change the way we think and change the way we act. Business as usual means watching thousands of people die every single day.”

—Dr. Lee Jong-Wook, WHO Director-General
United Nations General Assembly, New York
22 September 2003

This gap has fueled efforts by advocates to promote the production and export of generic drugs, and to convince governments and the private sector to ensure affordable access to essential medicines. While important progress has been made in reducing prices, drugs remain generally unavailable for most of those who need them.

U.S. Law and Antiretroviral Treatment

It is against this backdrop that the Bush Administration and the U.S. Congress moved in record time to promulgate the “United States Leadership Against HIV/AIDS, Tuberculosis, and Malaria Act of 2003,” a comprehensive new policy for U.S. global AIDS programs. The new policy authorized \$3 billion per year for five years and created a new ambassadorial level position of Global AIDS Coordinator, to be housed in the Office of the Secretary of State.

The new law includes non-binding “sense of Congress” targets for expanded treatment access, calling for programs to reach 500,000 individuals by the end of fiscal year (FY) 2004, 1 million by FY 2005, and

² UNAIDS, Report on the Global HIV/AIDS Epidemic, 2002

³ WHO, Treating 3 Million by 2005: Making It Happen, 2003

2 million by FY 2006. Starting in FY 2006 through FY 2008 (when the authorization ends), 55 percent of the authorized funds must be used for treatment, of which three-quarters must be for ARV therapy.

The legislation makes expanded access to ARV treatment one of the cornerstones of U.S. policy. U.S. funds are authorized for procurement, distribution, and monitoring of ARV drugs, for strengthening health care delivery systems, clinical training, care and treatment, and for treatment for opportunistic infections. Food and nutrition support are to be provided, as a component of ARV therapy, to individuals infected with and affected by HIV/AIDS.

Mechanisms and monitoring to ensure quality control and the sustainable supply of HIV/AIDS medicines are authorized in the new law, which also provides for monitoring to avoid the negative effects of drug resistance and illegal counterfeiting or black market sales of AIDS drugs. The law authorizes evaluation and surveillance of treatment programs, including resources for training and capacity development for improved collection and maintenance of HIV surveillance data.

By late August 2004, the Administration is required to submit to Congress a report on treatment programs supported by U.S. government agencies. In addition, not later than January 31 each year, the Administration must report on program activities of the preceding fiscal year, including an account of the number of patients receiving treatment for AIDS in each country that receives U.S. AIDS assistance.

Several pilot programs that include ARV treatment are authorized by the new law. The *Pilot Program of Assistance for Children and Families Affected by HIV/AIDS* will provide care and treatment – including ARV treatment – to children, parents, and caregivers in-

fectured with HIV or living with AIDS. Treatment programs are to be carried out by community organizations along with other program activities that address stigma, the property and inheritance rights of women, nutrition assistance, children's education, legal assistance, and counseling. The *Pilot Program on Family Survival Partnerships* will expand treatment through programs to prevent mother-to-child transmission of HIV (PMTCT). The pilot, which will provide care and treatment for children, parents, and family members, will be carried out through grants to local health organizations and international organizations.

In December 2004, the Centers for Disease Control and Prevention (CDC) issued a *Request for Proposals for Rapid Expansion of ARV Therapy Programs*. The proposals are for a five-year period, with \$115 million available for FY 2004. The proposals were required to describe plans for clinical care, drug and health commodities management, laboratory services, training, community mobilization and behavior change, and monitoring and evaluation. The proposals were also required to describe capacity building activities aimed at ensuring the sustainability of treatment programs.

[*Note: The Administration in February 2004 announced grant awards under this procurement to Catholic Relief Services, the Elizabeth Glaser Pediatric AIDS Foundation, the Columbia University Mailman School of Public Health, and the Harvard School of Public Health.*]

II. The On-the-Ground Experience

Because there are relatively few ARV treatment programs operating in resource-limited settings, there is a great deal to learn about what is needed to ensure their effectiveness. Gaining insights from programs already underway can help global AIDS advocates identify key issues for U.S. policies and programs aimed at meeting the goals for treatment access as specified in the new law.

Lessons Learned

To learn from those experiences, a panel representing five different organizations involved in ARV programs described successes, challenges, and obstacles faced by their programs. They highlighted the insights and lessons that their programs suggest for successful ARV scale-up. Discussion following the presentations also highlighted a number of concerns, including the need for more gender analysis⁴ in designing and implementing ARV treatment programs.

The organizations represented were the International HIV/AIDS Alliance (Alliance), the MTCT-Plus initiative of the Mailman School of Public Health at Columbia University (MTCT-Plus), Family Health International (FHI), Médecins Sans Frontières (MSF), and the AFL-CIO Solidarity Center. MTCT-Plus, FHI, and MSF are currently operating ARV treatment programs in resource-poor settings.

MSF has the longest experience in operating such programs. Having begun in 2000, it now operates programs in 19 countries, with 10,000 individuals currently receiving ARV treatment. MTCT-Plus provides care and treatment to HIV-positive women, their partners, and children through programs to prevent transmission of HIV from mothers to their infants. The initiative currently operates 12 programs in eight countries, enrolling 1,092 adults (75 percent of whom are women) and 511 children. Five percent of those in the program are receiving ARV treatment.

FHI's treatment programs began operation in 2003 in Ghana, Kenya, and Rwanda. As of early December, 2,382 individuals had received comprehensive HIV care, including treatment for opportunistic infections and TB. Nearly 15 percent, or 353 of those receiving care, have been placed on ARV therapy.

The International HIV/AIDS Alliance is working with organizations operating ARV treatment programs in three countries to develop models for community engagement. The AFL-CIO Solidarity Center works with trade unions around the world to respond to the AIDS epidemic.

[Note: The panelists' power point presentations can be found at: <http://www.icrw.org/projects/globalaidsaccountability/resources.htm>.]

Common Themes

A number of issues and themes emerged from the experiences of these organizations in providing ARV treatment. These include the following:

The critical importance of community and PLHA engagement. Each organization reported that engaging the community and PLHAs is an essential element of ARV treatment programs, irrespective of the venue or approach. Community engagement helps to reduce HIV/AIDS-related stigma and discrimination, relieves overburdened public health facilities, and provides support for care, treatment, and prevention. To be engaged, the community must have information about treatment so that it understands the benefits and challenges involved. This is described as "treatment literacy." The experience of these programs confirms the importance of tapping community resources and facilitating communication between the community and clinical staff, PLHA groups, and NGOs. Programs are strengthened by mobilizing community resources for education and advocacy for effective treatment

⁴Gender analysis is a form of social analysis that examines the differential impacts on men and women of policies, programs, and legislation that result from the widely-shared expectations and norms within a society about their respective roles, rights, and responsibilities.

policies, as well as for planning, implementing, and evaluating the treatment programs themselves. MSF supports advocacy by communities on behalf of PLHAs to ensure that they can receive appropriate care without stigma or discrimination. This means including advocacy as an integral activity within treatment programs. MSF also supports community advocacy for national ARV treatment policies and programs, which corresponds to its own international advocacy on access to essential medicines. The Alliance has found that community engagement contributes to rebuilding networks, norms, and community cohesion in areas where HIV/AIDS is unraveling the social fabric of society.

Drug procurement. Each organization highlighted difficulties related to drug procurement, particularly with respect to generic drugs. MSF primarily uses generic drugs, consistent with its determination to treat as many people as possible. The organization currently provides first-line ARV treatment for \$1 per patient per day. MTCT-Plus reported that there is no guidance at the global level on generics and concurred with FHI on the complications related to funding and cost recovery for ARVs, and management of drugs – including distribution, logistics (transportation and inventory management), and secure storage to avoid theft. FHI has used funds from its corporate foundation to underwrite the purchase of ARVs for its current programs. MSF has produced in-depth reports and guidelines related to ARV pricing and procurement.

Funding and donor action. Financial support for drug procurement is urgently needed. The organizations receiving government funding for their ARV programs reported that funding for drugs had not been provided. Support by donors should be aimed at supporting national governments to develop and implement national treatment programs through strengthening public health sectors. Donor coordination and fulfillment of agreed-upon commitments are also of paramount importance.

Stigma. The involvement of PLHAs in HIV/AIDS programs helps to overcome the stigma associated with HIV/AIDS and the discrimination that typically

accompanies stigma. Stigma prevents individuals from seeking to learn their HIV status – an essential step in expanding treatment access. The programs run by these organizations foster a supportive clinical environment as an important ingredient in efforts to overcome stigma. FHI used formative research to assess knowledge and attitudes of health workers and used the findings to help the workers become aware of the effects of stigma and how they might be contributing to it.

Patient selection. In several programs, patients are selected for treatment by committees, using pre-defined eligibility criteria. In most cases, the committees include community representatives and clinicians. Criteria for ARV therapy in MSF programs are a CD4 count of less than 200 for adults and less than 15 percent for children. Eligibility committees in MSF programs also consider the prior attendance by the individual at health care programs. MTCT-Plus eligibility criteria are based on a combination of CD4 count and WHO's staging system for HIV infection and disease. Eligibility includes all patients in clinical stage IV, those in stage II or III with CD counts below 350, and all patients with CD4 counts below 200. The experience of these programs suggests that patient selection criteria and methods will be a key issue in scaling up, as eligibility committees may not be practical on a larger scale.

Treatment adherence. Each program has demonstrated very high rates of adherence by patients to the required treatment regimen. Both MTCT-Plus and MSF reported adherence rates in excess of 90 percent. FHI's programs are built on principles of chronic disease management, which strengthen the motivation of the patient and family to maintain wellness and adhere to treatment requirements. Chronic disease management involves active patient and family participation. It requires the cultivation of a long-term, interactive relationship, with patient and health providers working as a team. MSF requires or strongly encourages each patient receiving ARV therapy to have a partner or assistant to provide support. The family-centered approach of MTCT-Plus, with a multidisciplinary team of treatment and care

providers, contributes to the high adherence rates that have been evident in its programs.

Service delivery. The development of standards and standard operating procedures are essential for establishing and operating treatment programs in resource-constrained locations. At the same time, programs must be adapted to local settings. Based on three years of experience in providing ARV treatment, MSF strongly advocates for simplification of treatment as essential to scaling up programs. The organization is developing simplified guidelines for ARV treatment and monitoring. MSF has found that an important step toward simplifying treatment is the use of fixed dose combination drug formulations.

To address the various dimensions of effective treatment, MTCT-Plus fields multidisciplinary teams to provide comprehensive HIV primary care. FHI's approach is to establish partnerships with governments, clinical care facilities, PLHA, and community support groups and NGOs for referral of patients to necessary services.

Human resources and capacity building. The scaling-up of ARV treatment will depend heavily on the availability of trained individuals to carry out the programs. All of the programs have developed resources to guide and support the development and administration of ARV treatment programs. The MTCT-Plus initiative has developed a clinical manual and a patient data manual, along with training materials on numerous topics. The Alliance worked with the World Health Organization and other collaborators recently to publish the "ARV Toolkit: A Public Health Approach for Scaling Up Antiretroviral (ARV) Treatment." FHI offers a variety of tools, including a curriculum on HIV/AIDS care and treatment and guidelines for ARV treatment.

Besides guidelines and training, the programs also provide ongoing technical assistance and support. FHI, for example, has established a system for electronic communications between site-based clinicians

in Rwanda and clinical experts at FHI offices in the U.S. and the Institute of Tropical Medicine in Belgium. The system provides support for difficult-to-manage cases.

Lessons Learned. Scaling-up of ARV treatment programs should include a close examination of current projects and certain ARV delivery systems based in the U.S. Some lessons learned from U.S. delivery systems include:

- ▶ Political will: Prevention and education efforts must be embedded in the culture.
- ▶ Fighting stigma is a never-ending battle and must be evaluated and re-evaluated on a continual basis.
- ▶ All efforts must be integrated into the broadest community possible.

Other scale-up issues. A wide range of other issues were identified by one or more of the organizations. These include the need to integrate HIV and TB services and develop improved diagnostic tools for TB/HIV co-infection; to develop treatment for children; to strengthen nurse-based care; to address sexual violence; and to develop rapid lab monitoring tools. AFL-CIO stressed that the workplace is a common place to initiate comprehensive ARV treatment programs if there is political will. The programs must include national policies for workers rights and a focus on building capacity of all business leaders.

"3 by 5" Campaign – World Health Organization Presentation by Nelle Temple Brown

WHO and UNAIDS recently launched a global initiative to have three million people in developing countries on antiretroviral therapy by the end of 2005 ("3 by 5"). The long-term goal of the initiative is to achieve universal access to antiretroviral therapy (ART) as a human right. The "3 by 5" target originated with the 2001 United Nations General Assembly Special Session on AIDS (UNGASS) target that stated "we should be able to treat 50 percent of those who need treatment (clinical AIDS, CD4 < 200) by 2005."⁵

⁵ United Nations General Assembly, "Declaration of Commitment on HIV/AIDS," 2001

WHO's strategy will be to catalyze rapid uptake of ART in communities where it is needed now, but is not widely accessible, by adopting a two-pronged approach of (1) supporting countries to recognize and respond to the HIV/AIDS treatment gap and leverage resources to enable ART to be scaled up rapidly in line with the 3x5 target and (2) simplifying and standardizing ART as much as possible (without compromising effectiveness) so it can be universally scaled up and delivered in resource-constrained settings.

The initiative is being carried out on an emergency basis and includes particular attention to coordinating and streamlining WHO internal procedures. The WHO strategic framework includes five categories and 14 elements:

1. Global leadership, alliances and advocacy (elements 1-4)
2. Urgent, sustained country support (elements 5-8)
3. Simplified, standardized tools for delivering antiretroviral therapy (elements 9-11)
4. Effective, reliable supply of medicines and diagnostics (element 12)
5. Rapidly identifying and reapplying new knowledge and successes (elements 13-14)

Additional efforts of the initiative include ongoing negotiation and coordination with WHO partners. Budgets and workplans for 2004-2005 are in the process of being approved, and financing is being secured. Milestones in the initiative will be reported at the International AIDS Conference in Bangkok in July 2004.

More information about the "3 by 5" Campaign is available at www.who.int/3by5.

III. Essential Elements of Scale-Up Strategy as Outlined by Participants

The participants agreed that a scale-up strategy should involve the following as key elements. They are divided into program related issues and principles and are in no particular order.

Program Issues

- ▶ **Approaches must simplify, adapt and decentralize treatment delivery.** Any scale-up strategy must support models that are simple, adaptable, decentralized, and transparent. They should also make use of existing capacity, entry points for care and treatment, and funding streams. The strategy should be driven by local needs and local context. All minimum standards of care and diagnostics must be reviewed and adapted for each country setting. Fixed dose combinations have proven to simplify treatment and improve adherence and should be considered as key to successful scale-up of ARV treatment.
- ▶ **Community mobilization and PLHA involvement must be a centerpiece of any scale-up strategy.** Community involvement must be substantive and ensure full participation by civil society organizations in the design, delivery and evaluation of ARV treatment programs, especially at the country level. Adequate resources must be made available to support community mobilization and PLHA involvement. Resistance to involvement of PLHAs and associations of PLHAs must be addressed and overcome, and the rights of PLHAs must be protected. In addition to making PLHA involvement a fundamental principle of its own programs, the U.S. should be in the forefront in supporting and facilitating PLHA involvement in multilateral and country-level policies and programs.
- ▶ **Drug procurement should be competitive, transparent, and non-corrupt.** Treatment programs should support open competition between generic and branded pharmaceutical agents so that people have the right to procure lifesaving AIDS medications at best world prices. The strategy should provide full transparency in drug procurement and should follow the World Health Organization's guidelines for antiretroviral medicines. Efforts should be made to eliminate drug sector corruption, including establishment of an international drugs and commodities anti-corruption program.
- ▶ **U.S.-supported ARV treatment programs should have a global reach.** The strategy should provide for treatment beyond the focus countries of the President's Emergency Program (PEPFAR) to include additional nations, such as India, where the epidemic is spreading most quickly.
- ▶ **ARV treatment programs must address barriers to access as well as the multisectoral dimensions of the epidemic.** The strategy for ARV treatment scale-up should include measures to ensure that potential barriers – such as violence, stigma and discrimination – do not prevent access to treatment, which begins with testing for HIV. Design of testing and treatment programs should include gender analysis, that is, analysis that focuses on the way the epidemic affects men and women differently as a result of society's expectations of their proper roles and responsibilities. The strategy must ensure that people receiving ART also have access to clean water, a stable food supply, immunizations, and antibiotics; all of this will help reduce basic illnesses that lower overall quality of health. Psychosocial support services are also needed. There is an urgent need for resources and activities related to HIV/TB co-infection.
- ▶ **Operational ARV treatment-related research and development must be supported.** A successful scale-up strategy must involve a research and development component that examines such questions as fixed dose

combination, minimum standards of care and diagnostics, diagnostic tools, and pediatric formulation. Specific needs and priorities for operational research should be identified and implemented. Among those is a need for further research to improve adherence and reduce toxicity.

Principles

- ▶ **Human rights and equity concerns should be fundamental in determining access to ARV treatment.** Respect for human rights must be a cornerstone of any strategy. A scale-up strategy should be women- and family-centered, include measures to ensure non-discrimination, and remove barriers to access for vulnerable populations. Gender analysis and priority attention to ending gender violence should be included and the voluntary nature of testing should be safeguarded. The strategy should also ensure equitable access to other care services for PLHAs and those affected by HIV/AIDS. Equity considerations should help guide decisions about resource allocation within U.S. ARV treatment programs.
- ▶ **Coordination within the U.S. government and with other governments, civil society, and the private sector should be a prerequisite for all programs to increase impact and avoid duplication.** Serious attention must be given to ensuring coordination and coherence across U.S. government global AIDS programs. U.S.-supported treatment programs should be coordinated with other global strategies and initiatives, as well as coordinated at the country level. The strategy should endorse a joint effort amongst all governmental and civil society players, particularly at the in-country level. It should
- outline a concrete and credible plan for donor coordination that includes mechanisms for coherence among donors and for involving all key stakeholders in country-level consultations. The strategy should identify remedies for countries where structural adjustment programs interfere with effective scale-up of ARV treatment.
- ▶ **The strategy must ensure local ownership by involving key stakeholders at the country level in the design, implementation, and evaluation of treatment policies and programs.** While affirming an important role for a variety of sectors and stakeholders, the public sector must be the principal actor in ARV treatment programs overall to reach the widest clientele.
- ▶ **Steps to ensure the sustainability of programs should be integral to all U.S.-supported treatment programs.** Sustainability rests heavily on training and infrastructure development. The strategy should ensure that local health providers (nurses, midwives, traditional healers, etc.) are utilized in ARV distribution in support of these existing relationships within communities. This may include priority access to treatment for health providers. Community engagement in treatment education and treatment support is critical to ensuring sustainability, as is a major emphasis on human capacity development and strengthening of organizations.
- ▶ **The measure of the success of expanded treatment access should encompass more than just the number of individuals receiving ARV therapy.** Monitoring and evaluation efforts must be driven by all key program elements and not only by target numbers outlined in the strategy.

IV. Conclusions

The consultation confirmed that providing ARV treatment in resource-poor settings is feasible, complex, and challenging. The high rate of adherence in the experiences to date is encouraging, and those involved in the programs are able to identify what works and what must be addressed to expand the programs to treat the millions of people who still lack access to ART. All agree that attention to clinical issues is critically important, but that a wider range of concerns, including social issues, are also key to successful scaling-up of programs.

Discussion among consultation participants identified several key treatment-related concerns that require more priority attention in government policies and programs. These include integration of gender analysis, HIV/AIDS-related stigma and discrimination, guidelines for responding to co-infection of HIV/AIDS and tuberculosis, and operations research. Continued advocacy is also needed to ensure that the U.S. funding commitments are fulfilled and sustained.

Disagreement between many advocates and policymakers continues over a number of issues related to scale-up of ARV treatment. These include disputes regarding application of trade policy related to intellectual property rights, policies on HIV prevention programs, and resource allocation for community engagement and mobilization.

Several process concerns were also identified as important to ensure effective policies and programs. The government process for awarding grants needs to be highly transparent. To ensure local ownership and sustainability of programs, mechanisms and procedures are needed to ensure civil society involvement in the design, implementation, and evaluation of strategies and programs. National treatment strategies, where they exist, should serve as the basis for U.S.-supported treatment programs. A donor code of conduct should be considered, which would establish international standards for cooperation, collaboration, and non-duplication of efforts by multiple donors.

Finally, the consultation affirmed the importance of open and consistent dialogue among all parties—government, civil society organizations (especially PLHA groups) and the private sector—as an element for effective policies and programs. Advocates recognized and fully support the need to increase understanding of treatment issues within the global AIDS advocacy community and to expand the circle of those working to close the treatment gap and extend the lives of millions of people who live where treatment is not yet available.

Glossary

ARV	Antiretroviral drugs (ARV) inhibit the reproduction of retroviruses – viruses composed of RNA rather than DNA. The best known of this group is HIV, human immunodeficiency virus, the causative agent of AIDS. http://www.ehendrick.org/healthy/000124.htm
ART	Antiretroviral therapy. A combination of antiretroviral drugs for treatment of HIV and AIDS.
3TC	Lamivudine. An antiretroviral drug, commonly used in combination with other drugs for treatment of HIV.
CD4 count	A count of the number of CD4-positive lymphocytes in the blood. The most commonly used surrogate marker for assessing the state of the immune system. As CD4 cell count declines, the risk of developing opportunistic infections increases. The normal range for CD4 cell counts is 500 to 1500 per cubic millimeter of blood. http://www.books.md/C/dic/CD4cellcount.php
d4T	Stavudine. An anti-HIV treatment in the class of drugs called Nucleoside Reverse Transcriptase Inhibitors (NRTIs). The body breaks down these drugs into chemicals that stop HIV from infecting uninfected cells in the body, but they do not help cells that have already been infected with the virus. http://www.aegis.com/factshts/network/simple/stav.html
FDC	Fixed-dose combination
NVP	Nevirapine. An antiretroviral commonly used in combination with other antiretroviral drugs to treat HIV.
Viral load	The number of viral particles (usually HIV) in a sample of blood plasma. HIV viral load is increasingly employed as a surrogate marker for disease progression. http://www.books.md/V/dic/viralload.php
WHO staging system	Stage I – Primary Infection Stage II – Clinically Asymptomatic Stage III – Symptomatic HIV infection Stage IV – Progression from HIV to AIDS

Appendix I



U.S. Strategy for Rapid Scale-Up of ARV Treatment: Advocacy Issues and Concerns

Friday, December 12, 2003
9 a.m. to 5 p.m.

Methodist Building,
100 Maryland Avenue, N.E.
Washington, DC 20002

Key question: What are the essential elements of a viable U.S. strategy for rapid scale-up of ARV treatment that must be included in the comprehensive, five-year U.S. global AIDS strategy that, under the new law, the Administration must submit to Congress in February?

Agenda

- 9:00 Welcome, background, and introductions
- 9:20 Overview of the Status of the Strategy Development
Report on meeting with Ambassador Tobias and other Administration officials
- 9:45 Congressional Perspectives
What does Congress expect with regard to the strategy? How will the strategy dovetail with the election year legislative process?

Peter Smith, House International Relations Committee
- 10:30 Coffee Break
- 10:45 Potential Models of ARV delivery: strengths, weaknesses and concerns
Mandeep Dhaliwal, International HIV/AIDS Alliance
Tom Hardy, MTCT-Plus, Mailman School of Public Health, Columbia University
Mary Lyn Field, Family Health International
Rachel Cohen, Médecins Sans Frontières
Rob Lovelace, AFL-CIO
- 12:30 Lunch break (to be provided on-site)
- 1:00 Presentation on "3 by 5" Treatment Initiative
Nelle Temple Brown, External Relations Officer
World Health Organization

- 2:00 Civil Society Recommendations on Essential Elements of a Viable Strategy to Meet Targets for ARV Treatment
A discussion to identify, from the global AIDS advocacy community’s perspective, what essential elements for effective ARV delivery must be included in the U.S. global AIDS strategy that is due to be submitted to Congress in late February. The discussion will also seek to identify how the global AIDS advocacy community can best ensure that those elements are included in the strategy and, by extension, in U.S. global AIDS policies and programs.
- 3: 45 Coffee
- 4:00 Dialogue with Dr. Joe O’Neill, Deputy Global AIDS Coordinator
A discussion about the essential elements of the strategy identified earlier in the day by the global AIDS advocacy community.
- 5:00 Adjourn

Appendix II

U.S. Strategy for Rapid Scale-Up of ARV Treatment: Advocacy Issues and Concerns

December 12, 2003

Panelists

Rachel Cohen, U.S. Director
Campaign for Access to Essential Medicines
Médecins Sans Frontières

Dr. Mandeep Dhaliwal
Senior Programme Officer: Care & Support
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Robert E. Lovelace
HIV/AIDS Program Coordinator
Solidarity Center, AFL-CIO

Appendix III

U.S. Strategy for Rapid Scale-Up of ARV Treatment: Advocacy Issues and Concerns

Friday, December 12, 2003

Participant List

Sherry Ayres Africa Action	Geeta Rao Gupta International Center for Research on Women
Gretchen Bachman Family Health International	Julie Hantman HIV/AIDS Public Health Policy, Bioethics
Kathleen Barnett International Center for Research on Women	David Haroz UNAIDS
Sean Barry Global Justice/Student Global AIDS Campaign (SGAC)	Ernest Hopkins San Francisco AIDS Foundation
Bonnie B. Berry International AIDS Trust	Zoe Hudson Open Society Institute
Paul Boneberg Global AIDS Action Network	Jodi Jacobson CHANGE
Heather Boonstra AGI	Delisa James NMAC
Rachel Cohen Médicins Sans Frontières	Sarah Kambou International Center for Research on Women
Helen Cornman Consultant	Asma Lateef Bread for the World
Barbara de Zalduondo Synergy Project	Rob Lovelace American Center for International Solidarity
Mandeep Dhaliwal International HIV/AIDS Alliance	Daniel Malleborgina Catholic Medical Mission Board (CMMB)
Mary Lynn Field-Nguer Family Health International	Hilary Marston Gates Foundation
Janet Fleishman Consultant	Marsha Martin AIDS Action
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Participant List *(continued)*

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