

MEMO

To: Ambassador Eric Goosby
From: Global AIDS Roundtable Treatment Working Group
Co-Chairs: Matthew Kavanagh, Health GAP, matthew@healthgap.org, 202 355-6343
Christine Lubinski, IDSA, clubinski@idsociety.org, 703-299-5027
CC: Jack Lew/DOS, Jeffrey Crowley/ONAP
Re: Recommendation for US Treatment Target
Date: October 15, 2009

Dear Ambassador Goosby:

Following up on our recent meeting regarding PEPFAR treatment efforts, we would like to thank you for your work in continuing the essential scale-up of access to anti-retroviral treatment. We would appreciate the opportunity to engage with you and your staff at your earliest convenience to discuss appropriate PEPFAR treatment targets.

Given the congressional mandate to prepare new treatment targets under the Lantos-Hyde Act of 2008 [PEPFAR II]¹ we write to urge you to promote a bold treatment target number. It is clear that under current methods of counting, PEPFAR is on track to quickly meet and surpass 3 million people supported on treatment. However, as you are aware, we have much further to go to reach all those individuals who need treatment now and who will need it in the coming years.

Without continued acceleration of the treatment targets, there are millions who are likely to succumb to this disease with tragic loss of life and tragic set backs to their families and communities. An analysis by Walensky et al suggests that PEPFAR support that allows only linear expansion in antiretroviral treatment would result in 1.2 million avoidable deaths in the next 5 years in South Africa alone.²

As such, we urge you to set a treatment target for PEPFAR to reach **6 million people with treatment by 2013 and 7 million by 2014**. This treatment target:

- Continues U.S. leadership toward meeting global treatment needs.
- Can *clearly* be reached under authorized funding levels.
- Reflects the dedication to cost savings to which the administration has committed.
- Builds on treatment as an essential prevention tool.
- Meets Congressional intent that bold ARV scale up continue.
- Is consistent with in-country goals for PEPFAR-supported countries.

With a bold treatment goal of **at 6 million people**, you and other U.S. leaders can credibly say that the U.S. has a clear plan to do “our part” and urge other donors to make similar commitments.

We are eager to engage with you and your staff for further discussion of this issue. We look forward to further dialogue.

Background Points:

By 2013 Millions More Will Need Treatment

According to the most recent WHO/UNAIDS/UNICEF report, 4 million people are receiving treatment—42% of those in immediate need under current WHO guidelines.³ However, these guidelines are set to be revised by the WHO in the near future, given a near universal consensus that ART should be initiated at a CD4 cell count of 350 and perhaps even earlier.³ This is currently the standard of care in the U.S. and there should be no second-best treatment standard. Under the new guidelines those in need of treatment will increase.⁴ With continued yearly growth in the patient population, achieving Universal Access goals of 80% coverage will likely mean reaching between 18 and 22 million PLWHA with treatment depending on how quickly treatment is rolled out and lives are saved.⁵

If the U.S. were to treat its traditional commitment of one-third of those in need, then the U.S. Universal Access treatment goals for 2013 could range between 6-7 million. At the end of the new U.S. Global Health Initiative in 2014, the goal might be 7-8 million.

Expanded ARV Treatment is HIV Prevention and Maternal & Child Health

The case for expanded treatment targets is not just based on lives saved per year. There is growing evidence that treating more people earlier could be one of the most powerful prevention tools currently available.⁶ In Sub-Saharan Africa, ARVs are also critical to addressing maternal and child mortality as HIV remains the largest cause of maternal mortality in some countries and community-wide coverage of ART is increasingly being shown to decrease non-HIV infant mortality, poverty, and deaths from diseases like TB. For example, antiretroviral treatment and co-trimoxazole prophylaxis provided to Ugandan adults was associated with a 95 percent reduction in mortality among HIV-infected adults, an 81 percent reduction in mortality of uninfected children and a 93 percent decrease in orphanhood.⁷ It is also important to note that Lantos-Hyde prioritizes scale-up of PMTCT programs and expansion of ART treatment for HIV-infected children—priorities that will not be realized in the absence of increased investment in ARV treatment and ambitious treatment targets.

ART Treatment Reduces TB Mortality

TB rates have exploded in sub-Saharan Africa, in large part due to HIV infection, making TB the leading cause of death of persons with AIDS worldwide, and contributing to a huge burden of TB disease in the community at large. Middelkoop, Wood and colleagues from the University of Cape Town have demonstrated marked decreases in TB incidence in a community with significant ART scale-up.⁸ The best weapon available to stave off TB mortality in HIV-infected individuals is access to ART.

Projected Funding Increases in PEPFAR Can Clearly Support Robust Treatment Goals

The Lantos-Hyde act authorized approximately \$39 billion for global AIDS programs—at least \$35 billion of which would be expected to go to bilateral programs under scale-up of both multilateral and bilateral efforts.⁹ Yearly scale-up of program funding (excluding NIH funding) is projected to increase from \$4.47 billion in FY08 to roughly \$9.5 billion by 2013.

**Projected PEPFAR II Bilateral HIV/AIDS Budgeting FY 2009-13
(Not including NIH spending or non-PEPFAR TB funding)**

FY 09	FY 10	FY 11	FY 12	FY 13	Total
\$5.028 billion	\$5.128 billion	\$7 billion	\$8.2 billion	\$9.5 billion	\$35 billion

Since Congress mandated that at least 50% of PEPFAR’s bilateral HIV/AIDS funding must be spent on treatment,¹⁰ with approximately \$5 billion more available per year in FY2013 as compared with FY2008, there will be an additional approximately \$2.5 billion to spend on treatment. Some of that, estimated at approximately 20%, will be spent on non ART-related expenses including nutrition and OI treatment, which would still leave approximately \$2 billion yearly for ARV treatment. Based on expected economies in per-person-per-year costs this new funding could support between 4.5 million and 10 million additional PLWHAs on treatment by the end of 2013.

Treatment Costs are Expected to Fall—Making A Bold Treatment Target Possible

In FY 2008, PEPFAR reports having spent \$1.57 billion on treatment, including ARV drugs, ARV services, and laboratory infrastructure,¹¹ which supported treatment for an estimated 2 million people in focus countries.¹² Thus, the per-person-per year cost in FY 2008 was \$800. This is roughly consistent with costs reported by PEPFAR at the 2009 Implementers Meeting.¹³ As such, even at current cost-levels many more can be treated by 2013.

HIV Treatment Cost pppy	Additional FY13 Treatment Budget	<u>Additional</u> People on PEPFAR II-Supported Treatment 2 Million	Total by 2013
Current: \$800	\$2 billion	2.5 million	4.5 million
Stover, <i>Futures</i> : ¹⁴ \$500	\$2 billion	4 million	6 million
Bemelmans, <i>MSF Malawi</i> : \$237	\$2 billion	8 million	10 million

As you and others have noted, however, PEPFAR programs can find significant cost savings as treatment scale-up continues. Ongoing price reductions for ARVs, task-shifting within the workforce, and reduced overhead both within the U.S. government and its implementing partners can continue the current trend. For example, Doctors Without Borders has had remarkable success in achieving treatment efficiencies and now reports that its per-patient treatment costs in Malawi were only \$237 per year (67% for ARVs, 14% of other essential drugs, 13% for staff and clinic costs, and 6% for laboratory costs).¹⁵

As such, a treatment target in line with expected cost savings is the only appropriate course. With an additional year under the Global Health Initiative, a 2014 target should be approximately 1 million more.

Improved Treatment & Early Initiation

In addition to significantly expanded treatment targets, PEPFAR must adopt clinical best practices, by moving away from use of toxic d4t-containing regimens to those containing tenofovir, increasing use of more expensive second-line therapies for patients experiencing drug resistance or severe adverse side effects, and initiating ART earlier.¹⁶ However, the increased cost of improved regimens may actually offset other costs, as improved durability, tolerability, and efficacy are likely to result in better adherence and treatment outcomes and reduce the need (and thus cost) for second-line.

PEPFAR II's Legal Framework for Treatment

The Lantos-Hyde act and accompanying Congressional Record and public statement clearly demonstrate a Congressional mandate to boldly expand access to treatment above existing levels. Under PEPFAR II's authorization language, "more than half" of bilateral aid under PEPFAR must be spent on treatment programs, including ARVs, opportunistic infections, and treatment-related nutritional support. PEPFAR's treatment target is required to increase based on appropriation levels and cost savings.¹⁷ Senators explicitly rejected a goal of 3 million people on treatment as insufficient.¹⁸ In addition, the Congress explicitly required targets that are in *addition* to any multilateral achievements.

Together, the Congressional Record is clear that bold treatment targets were intended.

NOTES

¹ The Tom Lantos and Henry J. Hyde United States Global Leadership Against HIV/AIDS, Tuberculosis, and Malaria Reauthorization Act of 2008, P.L. 110-293.

² Walensky RP, Wood R, Weinstein MC, et al. Scaling up antiretroviral therapy in South Africa: the impact of speed on survival. *J Infect Dis* 2008;197:1324-32.

³ Towards Universal Access: Scaling up priority HIV/AIDS interventions in the health sector – Progress Report 2009 [hereinafter 2009 Progress Report], available at http://www.who.int/hiv/pub/tuapr_2009_en.pdf.

⁴ 2009 Progress Report, Box 49, p. 73.

⁵ New guidance would be to roughly double the number of people needing treatment at the end of 2009 to 19 million. From there projecting the number of people who were infected seven or eight years earlier, means that approximately 2.8 million people will be added to per year. If deaths stay at 2 million a year and the status quo treatment rate of only 1 million more a year is maintained, the treatment queue would be approximately 23 million in 2013. However, if treatment were doubled to 2 million more a year and deaths were reduced to 1 million a year, the treatment queue would contain 27 million people in 2013

⁶ Reuben M Granich et al., *Universal voluntary HIV testing with immediate antiretroviral therapy as a strategy of elimination of HIV transmission: a mathematical model*, 373 *Lancet* 48-57 (2009).

⁷ Mermin J, Were W, Ekwaru JP, et al. Mortality in HIV-infected Ugandan adults receiving antiretroviral treatment and survival of their HIV-uninfected children: a prospective cohort study. *Lancet* 2008;371: 752-9.

⁸ K. Middelkoop, R. Wood, L. Myer, A. Whitelaw, G. Kaplan, J. McIntyre, LG Bekker, Widespread ART is associated with decline in TB prevalence, Late breaker abstract no. WELBB105, IAS, 2009.

⁹ After subtracting \$9b specifically directed to TB and Malaria programs, PEPFAR II authorized \$39 billion for HIV/AIDS funding. Of that, multilateral funding might be expected to scale up from current levels of \$900m for the Global Fund to as much as \$2.5b by 2013. Since HIV/AIDS programming at the Global Fund currently comprises 54% of the lifetime budget to recipients with the remainder going to malaria (30%) and tuberculosis (16%) we would expect the “AIDS” funding to include approximately \$4b, leaving \$35b for the U.S.’s bilateral HIV/AIDS programming.

¹⁰ Section 401(c) “FUNDING ALLOCATION.—For each of the fiscal years 2009 through 2013, more than half of the amounts appropriated for bilateral global HIV/AIDS assistance pursuant to section 401 shall be expended for—

- (1) antiretroviral treatment for HIV/AIDS;
- (2) clinical monitoring of HIV-seropositive people not in need of antiretroviral treatment;
- (3) care for associated opportunistic infections;
- (4) nutrition and food support for people living with HIV/AIDS; and
- (5) other essential HIV/AIDS-related medical care for people living with HIV/AIDS.”

¹¹ Program Summary Budget, Fiscal Year 2008, available at <http://www.pepfar.gov/about/opplan08/102042.htm>. An additional \$.32 billion (roughly 20%) was added for central procurement, supply chain, technical support, New Partners Initiative, strategic information, management & staffing, policy analysis, and systems strengthening activities.

¹² Total is only on Focus Countries. PEPFAR, Treatment 2008, available at <http://www.pepfar.gov/about/c19384.htm>.

¹³ Mozambique and Cote d’Ivoire treatment costs of \$607 and \$795/pppy presented, “PEPFAR Costing and Cost Projection Efforts,” John Blandford, Office of the U.S. Global AIDS Coordinator, *Windhoek, Namibia, 11 June 2009*.

¹⁴ Based on personal communication and “The Cost of Anti-Retroviral Therapy: Present Commitments and Future Needs, <http://futureartcosts.org>

¹⁵ Marielle Bemelmans et al., Abstract – Cost analysis of an ARV care programme reaching universal access in Thyolo, Malawi, 5th IAS Conference on HIV Pathogenesis, Treatment and Prevention 19-22 July 2009 available at <http://www.ias2009.org/pag/Abstracts.asp-x&AID=3291>.

¹⁶ According to the Clinton Foundation, the newer regime of TDF + 3TC + EFV (300/300/600mg) now costs \$210/pppy versus \$89/pppy for d4T (30mg) + 3TC (150mg) + NVP (200mg). 2009 Antiretroviral (ARV) Price List, available at <http://www.clintonfoundation.org/files/chairvpricelistaugust2009english.pdf>.

¹⁷ Section 401(c) and 401(d)

¹⁸ e.g. Senator Coburn, Statement on Manager’s Substitute, S. 2731 PEPFAR Reauthorization, July 14, 2008.