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# Prevention Failure: The Ballooning Entitlement Burden of U.S. Global AIDS Treatment Spending and What to Do About It By Mead Over

#### Abstract

U.S. global AIDS spending is helping to prolong the lives of more than a million people and is widely seen as a foreign policy and humanitarian success. Yet this success contains the seeds of a future crisis. Life-long treatment costs are increasing as those on treatment live longer, and the number of new HIV infections continues to outpace the number of people receiving treatment. Escalating treatment costs coupled with neglected prevention measures threaten to squeeze out U.S. spending on other global health needs, even to the point of consuming half of the entire U.S. foreign assistance budget by 2016.

This paper describes the dimensions of these problems and argues that the United States has unwittingly created a new global "entitlement" to U.S.-funded AIDS treatment that currently costs about \$2 billion per year and could grow to as much as \$12 billion a year by 2016—more than half of what the United States spent on total overseas development assistance in 2006. And the AIDS treatment entitlement would continue to grow, squeezing out spending on HIV prevention measures or on other critical development needs, all of which would be considered "discretionary" by comparison.

Over suggests ways to substantially restructure the President's Emergency Plan for AIDS Relief (PEPFAR) in order to avert a crisis in which Americans would have to choose among indefinitely increasing foreign assistance spending on an entitlement, eliminating half of other foreign aid programs, or withdrawing the medicine that millions of people depend upon to stay alive. His suggestions include consolidating treatment success and leveraging treatment for prevention by making the extension of further AIDS treatment financing conditional on success in both treatment adherence and prevention outreach; shifting to a focus on prevention by underwriting male circumcision efforts and expanding HIV testing and counseling for couples more so than for individuals; and intensifying the effects of prevention interventions by mapping high risk locations and targeting them with tailor-made prevention programs.

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### Prevention Failure: The Ballooning Entitlement Burden of U.S. Global AIDS Treatment Spending and What to Do About It

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#### I. Introduction: Build on PEPFAR

Although it was unknown as recently as the 1980's, AIDS is now the most notorious disease in the world. In the United States children study the HIV/AIDS epidemic in primary school and learn HIV prevention methods in high school.<sup>2</sup> Among some poor illiterate populations in the severely affected countries of Africa, more people correctly identify sex as a means of HIV transmission than know that mosquitoes transmit the ancient scourge that kills almost as many Africans.

The notoriety of the AIDS epidemic is due to many factors. The fact that it first came to attention as a disease that primarily affected gay men in the US and other rich countries is certainly one important reason: Gay men proved to be extraordinarily articulate in publicizing the ravages of the disease and in lobbying for public resources to study and treat it. The long incubation period of the virus allowed persons living with AIDS to speak and write about their suffering for years, possibilities which were less available to sufferers from more quickly fatal illnesses.

The appearance in these personal narratives of both sex and death contributed to their fascination. HIV-infected blood supplies spread the disease to many transfusion recipients in rich countries and led to scandals and more publicity. The creation of a specialized international agency called first the Special Programme on AIDS, then the Global Programme on AIDS and currently UNAIDS provided salaried positions for people whose job it was to publicize this sole disease. The novel challenges of research on the causative agent, one of a class of little understood pathogens called "retroviruses", engendered enthusiasm in the medical and biological research communities. Based on this rapidly evolving research, multinational pharmaceutical firms discovered new drugs to combat the disease and profited from selling those drugs in rich and sometimes in poor countries.<sup>3</sup> And last, but not least, the fact that the virus and its consequences spread in many parts of the world despite what seemed like the best efforts to control it.

Although the AIDS epidemic is no longer a growing public health problem in the US or other rich countries, UNAIDS estimates that over 33 million people are infected and over 2 million deaths occur every year (UNAIDS 2007). While the robust economic growth of heavily affected countries like Botswana and South Africa suggests that AIDS does not have immediately catastrophic impacts on economic growth<sup>4</sup>, the fact that it can reduce life expectancy by decades is by definition a catastrophic impact on economic well-being and development. AIDS is decimating the professional classes of the worst affected countries (Hamoudi and Birdsall 2004). Furthermore, the long-term impact of lower life expectancy and high rates of orphanhood are still unknown. One study has suggested that by the year 2080 orphanhood in South Africa might reduce its income per capita to less than half of its current level. (Bell, Devarajan, and Gersbach 2004:96-133) Growing awareness of these impacts of AIDS may have contributed to President Bush's decision to propose an initiative to combat AIDS in poor countries in the same 2003 State of the Union address in which he announced his intention to invade Iraq.<sup>5</sup>

In response to a proposal from the White House, US Congress launched the US Global AIDS Initiative by passing the United States Leadership against HIV/AIDS, Tuberculosis and Malaria Act of 2003 on May 27, 2003 (2003, 108-25)<sup>6</sup>. The act required the President to establish the position of Global AIDS Coordinator within the Department of State, rather than in USAID where previous US-funded AIDS assistance had been managed. The Coordinator, Ambassador Randall Tobias, fulfilled his mandate to present to Congress the US Five-year Global AIDS Strategy on February 23, 2004. He gave the strategy the title: "The President's

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<sup>&</sup>lt;sup>2</sup> HIV is the acronym for the human immunodeficiency virus, which causes the acquired immune deficiency syndrome, or AIDS.

<sup>&</sup>lt;sup>3</sup> See note 14

<sup>&</sup>lt;sup>4</sup> For a recent contrary view on the economic benefits of AIDS treatment, see (Ventelou et al. 2008, 22:107-113)

<sup>&</sup>lt;sup>5</sup> See Radelet (2003) for a discussion of the shifting politics of Bush's foreign aid policy.

<sup>&</sup>lt;sup>6</sup> This paragraph draws on page 24 of the IOM report (Institute of Medicine 2007)

Emergency Plan for AIDS Relief' (PEPFAR) which today remains the name of the program (OGAC 2004). The strategy established the following three objectives:

- "To encourage bold leadership at every level to fight HIV/aids
- "To apply best practices within US bilateral HIV/AIDS prevention, treatment and care programs...
- "To encourage partners ... to coordinate ... [in order] to ensure the most effective and efficient use of resources." (OGAC 2004)

The strategy defined 15 "focus countries" for US HIV/AIDS assistance, which are listed in Table 1.

Table 1. Selected Economic and Health-Related Indicators of the PEPFAR Focus Countries

			GDP per	Life	Adult HIV/AIDS prevalence (ages 15 – 49)		Number of
C	Damidatian	Income	capita	expec-	Point	Danas	physicians
<b>Country</b> Botswana	<b>Population</b> 1,765,000	<b>status</b> Upper middle	<b>(US\$)</b> 8,920	tancy 35	<i>estimate</i> 24.1	<i>Range</i> 23.0– 32.0	<b>in 2003/4</b> 715
Côte D'Ivoire	18,154,000	Low	1,390	47	7.1	4.3–9.7	2,081
Ethiopia	77,431,000	Low	810	48		0.9-3.5	1,936
Guyana	751,000	Lower middle	4,110	63	2.4	1.0-4.9	366
Haiti	8,528,000	Low	1,680	52	3.8	2.2-5.4	1,949
Kenya	34,256,000	Low	1,050	47	6.1	5.2-7.0	4,506
Mozambique	19,792,000	Low	1,160	42	16.1	12.5 <b>–</b> 20.0	514
Namibia	2,031,000	Lower middle	6,960	46	19.6	8.6– 31.7	598
Nigeria	131,530,000	Low	930	44	3.9	2.3-5.6	34,923
Rwanda	9,038,000	Low	1,300	44	3.1	2.9-3.2	401
South Africa	47,432,000	Upper middle	10,960	52	18.8	16.8– 20.7	34,829
Tanzania	38,329,000	Low	660	44	6.5	5.8-7.2	822
Uganda	28,816,000	Low	1,520	48	6.7	5.7-7.6	2,209
Vietnam	84,238,000	Low	2,700	72	0.5	0.3-0.9	42,327
Zambia	11,668,000	Low	890	37	17	15.9– 18.1	1,264

NOTE: GDP = gross domestic product.

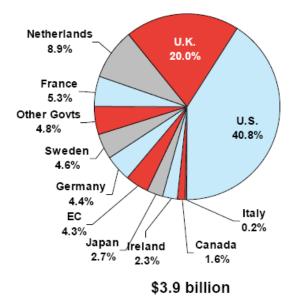
Source: (Institute of Medicine 2007) Tables 2-3, 2-4, pp. 59-61.

As a result of PEPFAR, the United States was the largest single contributor to the struggle to control the international AIDS epidemic in 2006 and 2007. (Kates, Izazola, and Lief 2007:10) In 2006 the US committed \$2.6 billion for AIDS, which was 47 % of the \$5.6 billion total from all donors, with the Netherlands in second place at 17% (page 9). As illustrated in figure 1, the US accounted for 41% of the \$3.9 billion that was actually disbursed (with the UK in second place at 20 %) (page 10). Most of this money was channeled through the US's President's Emergency Plan for AIDS Relief (PEPFAR), which can properly be described as the "largest global health initiative directed at a single disease that any nation has ever undertaken".(US Government 2007) For comparison, in inflation-adjusted dollars the US is spending more than 100 times as much per year now on AIDS in poor countries as it spent between 1967 and 1979 on the eradication of smallpox.<sup>7</sup>

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<sup>&</sup>lt;sup>7</sup> The US is estimated to have contributed about \$25 million over the 12 years of the smallpox eradication campaign or an average of about \$2.5 million per year (Levine 2004). In current dollars this would be about \$5 million per year which is less than one percent of the US's 2006 expenditures on AIDS.

# International AIDS Assistance: G8/EC & Other Donor Governments as Share of Total Donor Government Disbursements, 2006



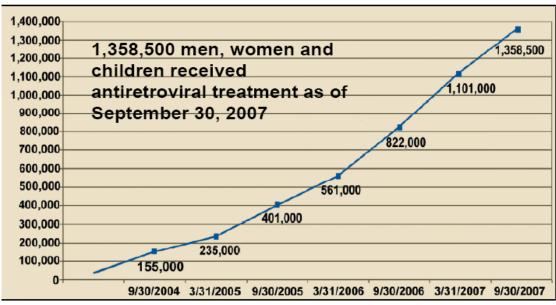
Source: (Kates, Izazola, and Lief 2007:10)

Figure 1. Shares of national donor disbursements to combating AIDS, 2006

The most remarkable achievement of the PEPFAR program has been its contribution to the provision of AIDS treatment to over 1.3 million patients in its 15 focus countries by September of 2007<sup>8</sup>. Furthermore, as Figure 2 shows, PEPFAR was able to accelerate constantly until March, 2007, adding more patients to its roles each six month period than it had the previous six months. However, it is sobering to note that the number of new infections in this period in these countries averaged about 1.4 million in every year, about three times the number of people who started therapy in the last year of the data.

The US foreign Assistance program is also the biggest single funder of the Global Fund to Fight AIDS TB & Malaria and the second biggest (after the United Kingdom) of the World Bank, the two most important multilateral sources of AIDS financing. Also US tax laws favoring the creation and operation of philanthropic foundations have enabled US foundations to dominate the world of foundation giving to fight AIDS.

<sup>&</sup>lt;sup>8</sup> Of the 1.4 million individuals receiving treatment, PEPFAR provided treatment directly to about one million and provided indirect support to the treatment of an additional 350,000. (OGAC 2008, Fourth Annual Report to Congress)



Source: (OGAC 2007)

Figure 2. Number receiving US-supported AIDS treatment in the 15 PEPFAR focus countries

Thus US AIDS policy under President Bush has established a record of success on AIDS treatment, to which the actions of the next US President will inevitably be compared. Presidential candidates choose to ignore AIDS policy at their peril. They can quietly continue the country on its present course. They can withdraw support from AIDS patients, risking a backlash of cynicism and skepticism regarding the country's ability to respect its commitments. Or, as outlined below, they can address the weaknesses of existing US AIDS policy and, in so doing, strengthen the U.S. reputation for contributing to the solution of global problems.

While there is a growing literature on the investment benefits of programs to combat AIDS, there is only weak support for the proposition that subsidized AIDS treatment for the poorest AIDS patients will stimulate national growth – except in the health sector where it is rumored to have substantially augmented doctors' incomes. The attempts to expand US support for AIDS treatment during the Clinton administration were justified on national security grounds. An innovation of the Bush presidency was to largely eschew national security as a justification for the PEPFAR program. Instead the Bush administration used the AIDS program as the prime international exhibit for its vaunted philosophy of "compassionate conservatism". As its name signifies, PEPFAR was originally justified primarily as an emergency plan. However, PEPFAR is creating entitlements which cannot be assumed by most of the recipient countries and is hard to justify on investment grounds. These features of PEPFAR suggest that it is really an international transfer program, comparable perhaps to US food assistance. Programs to redistribute consumption from rich-country taxpayers to the poor in developing countries constitute state supported international welfare programs.

Our recommendations to the next president are grouped under three headings: manage the AIDS treatment entitlement, prevent the future need for treatment and assure the "AIDS transition". <sup>10</sup>

<sup>10</sup> Box 1 summarizes the state of discussions at the time of this writing between the administration and congress on the content of the program that will follow PEPFAR.

<sup>&</sup>lt;sup>9</sup> The US constituency for US food aid is a coalition between supporters of altruistic aid to hungry people in developing countries and US farmers who benefit when the US buys the food to be donated overseas. The US constituency for the PEPFAR program has analogously consisted of a coalition between supporters of altruistic treatment for AIDS patients and US multinational pharmaceutical manufacturers who benefit when the US buys their products for donation overseas. The recent shift of US policy towards approval of the purchase of generic drugs from non-American sources weakens but does not vitiate this analogy.

<sup>10</sup> Box 1 suppositions the state of discussions at the time of this writing between the administration and

### Box 1 - How do the President and Congress think PEPFAR should be restructured? by Michael Bernstein, Center for Global Development

The law creating PEPFAR gave it legal authority for a five year period that expires at the end of 2008. With that date quickly approaching, the program is expected to be reauthorized for another five years by Congress before the end of this year. As part of the reauthorization process, a variety of key stakeholders have begun to offer their own recommendations on how PEPFAR should be reformed. This box summarizes the views of two particularly important and influential actors – President Bush and the US Congress:

#### President Bush

In May 2007, President Bush announced his support for \$30 billion in funding for the next phase of PEPFAR. He also proposed a set of goals for "PEPFAR II" that would place greater emphasis on prevention than PEPFAR I, and would slow the rate at which PEPFAR was enrolling new patients for treatment. Specifically, he has called for PEPFAR II to support: treatment for 0.5 million additional people; prevention of 5 million new infections; and care for 2 million people. The relative weighting of these goals is consistent with the recommendations in this chapter, although the prevention target is less ambitious than our proposal.

President Bush has also called for the US government to begin signing agreements called "partnership compacts" with countries that are receiving PEPFAR funds. The underlying goals of the compacts are: 1) To ensure that governments are investing their own resources in AIDS programs; 2) To formalize the relationships between PEPFAR and other stakeholders such as the government, other donors, civil society and the private sector; and 3) To implement AIDS programs in a way that supports broader development objectives, including gender equality and economic growth. The executive branch has not yet offered more details about how these partnership compacts will be implemented or which countries will be asked to sign them.

#### U.S. Congress

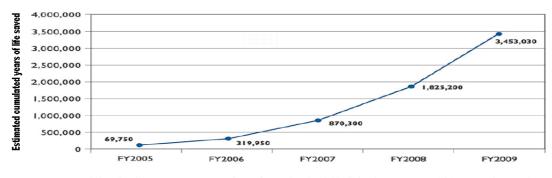
The House and Senate have both drafted bills that call for \$50 billion in funding for AIDS, TB and malaria over the next five fiscal years. Most of that money – roughly 80% - would go for AIDS programs. The Global Fund would receive up to one-fifth of the total, \$10 million over five years. The remaining bilateral AIDS funding would largely be free of the type of funding directives ("earmarks") that were mandated in the first five years of PEPFAR.

Congress has accepted President Bush's proposed targets for prevention and care, but they have changed the treatment target to 1 million and have added a new target – train 140,000 health workers. The Senate bill also includes targets on PMTCT and pediatric AIDS treatment.

The bills to reauthorize PEPFAR emphasize the importance of prevention more than original bill did. The original bill called for PEPFAR to spend 20% of its funding on prevention; the new PEPFAR bills stipulate that 20% should be the minimum spent on prevention. Both bills have also increased the prevention target - which has gone from preventing 7 million infections to preventing 12 million infections - more significantly than the treatment target - which has changed from treating 2 million people to 3 million people. Whereas the first phase of PEPFAR included a provision stating that 2/3 of sexual prevention funding had to be used for abstinence and be faithful activities, the current bills have no such provision but they do call for half of sexual prevention funding to be used for "behavior change" programs – a term that has not yet been clearly defined but clearly includes abstinence and be faithful activities.

As recommended in this chapter, the two bill calls for more funding for operations research and an increased emphasis on strengthening health systems. The Senate bill also mandates that PEPFAR conduct an impact evaluation to examine the effect of PEPFAR programs on indicators like incidence, prevalence, and mortality. Other key features of the two bills include: a clear recognition that PEPFAR must address the special vulnerabilities of women and girls, and better integration of nutrition and HIV programs.

PEPFAR will have added through 2009. (US Government 2007, Figure 4) according to their estimates, the program has purchased 870, 340 years of life by mid-2007 and will purchase an additional 2.5 million life years through 2009 (Figure 3). And there will be spillover benefits for others in these societies. For example, assuming the average patient has 2 children under 15 years old, and will have no new children while on ART, each of these extra years of life averts about two years of orphanhood.<sup>11</sup> That would be about 7,000,000 years of orphanhood averted through 2009, a laudable achievement.



Note: Calculations are based on methodology developed by the WHO, 2006. Total person-years-of-life added are based on the actual number of persons on ART in FY2004-FY2006 and projected numbers of people to be on treatment for FY2007 and FY2008.

Source: (OGAC 2007)

Figure 3 Estimated cumulated years of life saved through FY2009 due to PEPFAR support in 15 focus countries

#### B. US is contributing its fair share on AIDS - if not elsewhere

US citizens should be proud that their government has been the international leader in the altruistic effort to expand the availability of AIDS treatment. In view of the Bush administration's unwillingness to shoulder its share of the responsibility to prevent global warming, AIDS policy stands out as an area where the US has taken the lead in assuming responsibility for a global problem – if not always in the way other countries would have preferred.<sup>12</sup>

The three panels of Figure 4 present three views of the magnitude of the US effort to combat the international AIDS pandemic. Panel (a) shows that the US is second among OECD countries in the percentage of its total ODA budget that it devotes to AIDS. Panel (b) shows that the US contributes 45 % of all OECD aid on AIDS, which is the same as its share of OECD GDP, but almost twice its 24 % share of total aid from OECD countries.

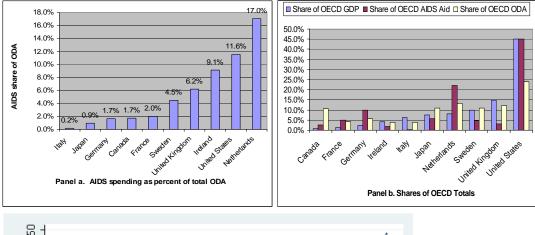
Panel (c) presents the data from the previous two panels against a "Fairness Frontier". A country on the frontier is giving a share of total OECD development assistance which is in proportion to its share of total OECD income or GDP. Such a country could be viewed as giving its "fair share". Countries above the frontier are more generous relative to other OECD countries and countries below it are stingier. The base of each arrow shows the fairness of each country's total aid contributions and the arrow point shows its fairness for AIDS. Panel (c) shows that, despite its large contributions, the US is less generous than most

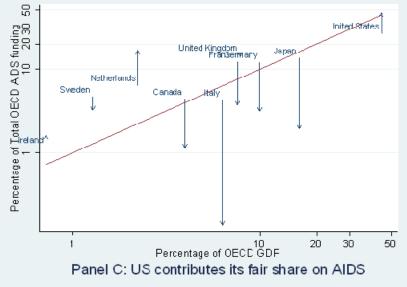
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<sup>&</sup>lt;sup>11</sup> Unfortunately people on ART have trouble getting access to family planning methods and so may not be able to prevent additional births even if they want to, as many do. Expansion of family planning services in conjunction with antiretroviral therapy is an urgent need. See Section VB for discussion of priority prevention programs.

<sup>&</sup>lt;sup>12</sup> For example, Pedro Chequer, the director of Brazil's AIDS program explained his country's refusal to accept US requirements to condemn prostitutes and promote abstinence-only prevention programs, with the following remark: "Obviously abstinence is the safest way to avoid AIDS. But it's not viable in an operational sense unless you are proposing that mankind be castrated or genetically altered, and then you would end up with something that is not human but something else altogether." (Rohter 2005)

countries on total aid and exactly on the Fairness Frontier" in its AIDS contributions. <sup>13</sup> On at least this measure, the United States is performing better on AIDS than on overall foreign assistance. – even if it compares less well on other dimensions of assistance. <sup>14</sup> <sup>15</sup>





Source: (Kates, Izazola, and Lief 2007)

Figure 4. The US has devoted a larger share of its assistance funding to AIDS than all but one of the other OECD countries

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<sup>&</sup>lt;sup>13</sup> One country's AIDS generosity can, by this measure, make another look stingy. For example, if the United Kingdom were to double its AIDS funding, total AIDS funding would be increased, so the US would be providing a smaller share of the total and the point of its arrow would be pushed below the "Fairness Frontier".

<sup>&</sup>lt;sup>14</sup> The direction of the arrow in Panel (c) of Figure 3 shows how the individual OECD country funds AIDS in comparison to its other international contributions. The US joins the Netherlands and Germany in revealing a preference for AIDS assistance over other types of ODA, as indicated by the upward directions of their arrows in the figure. Despite France's rhetorical promotion of assistance for AIDS treatment (http://www.ambafrance-uk.org/2nd-International-AIDS-Society.html,

http://www.africa.upenn.edu/Urgent\_Action/apic\_11098.html
), the shortness of its upward arrow in Panel
(c) reveals that it gives only slight preference to AIDS in comparison to other types of ODA. The other
OECD countries contribute smaller, sometimes much smaller, shares of AIDS assistance than of other types of aid.

For instance, on the environment dimension the Center for Global Development has ranked the US in last place for 2007 (<a href="http://www.cgdev.org/content/publications/detail/14716">http://www.cgdev.org/content/publications/detail/14716</a> ).

#### C. But US assistance has made little measurable progress on prevention

Each prevented HIV infection saves many years of life in the protected individual and also has spillover benefits for all of society. It has been estimated that each dollar that Thailand invested in its HIV prevention program saved \$43 dollars in avoided future treatment costs (Over et al. 2007, 21 Suppl 4:S105-S116;Revenga et al. 2006). By preventing these infections, Thailand also avoided millions of painful adult deaths and infected or orphaned children.

Despite the recognized priority of prevention in any disease control program, PEPFAR's enabling legislation first suggested, and then required, the agency to spend only 20 percent of its resources preventing future cases (Oomman, Bernstein, and Rosenzweig 2007b). Furthermore, PEPFAR was first asked, and then constrained, to spend two-thirds of those prevention resources on the A (abstinence) and B (be faithful) strategies, leaving only a third of the 20 percent, or less than 6 percent of overall funding, for use in reducing the riskiness of ongoing risky behavior (the "C" or condom-based strategy).

Since the 20 percent share for prevention was originally only a suggestion, PEPFAR actually spent more than 30 percent on prevention in its first year of operation. But as Figure 5 shows, in each subsequent year the share spent on prevention declined until in 2006 the share reached the mandated 20 percent. Part of the reduction in prevention's share was due to the scaling up of expenditures on treatment. But Figure 6 shows that the reduction in prevention share was accompanied by a reduction in the magnitude of prevention spending in nine of 15 countries. <sup>16</sup>

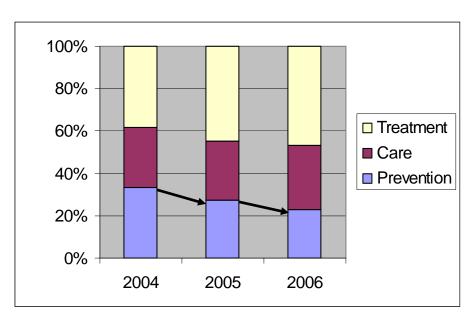
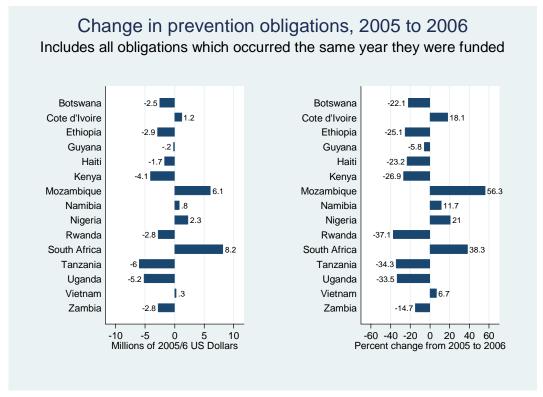


Figure 5. Prevention has declined from 33% to 23% of PEPFAR funding

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<sup>&</sup>lt;sup>16</sup> Data released by OGAC to the Center for Public Integrity includes no information on 2006 funding that had not yet been obligated at the end of 2006. However, the data do allow us to estimate the proportion of late obligations for funding years 2004 (15.8 percent) and 2005 (9 percent). In order to construct figure 6, which compares 2005 and 2006 funding, we have excluded the 9 percent 2005 funding which was not obligated in 2005. With this exclusion, the data show a reduction in the absolute amount of prevention spending in eight of 15 focus countries. Assuming that the percentage of unobligated funding at the end of 2006 was not much larger than the 9 percent that had been achieved in 2005, this conclusion is robust to the inclusion of that data.



Source: Author's calculations based on data from the Center for Public Integrity described in (Oomman, Bernstein, and Rosenzweig 2007b). See note 16.

Figure 6. PEPFAR spending on prevention declined in absolute terms in nine of 15 countries..

According to law, PEPFAR's objective has been to save 7 million HIV infections by 2010 in the 15 focus group countries. Over the five years of PEPFAR implementation that would be 1.4 million infections a year. But the total number of infections per year in these countries is estimated by UNAIDS to be about 1.8 million a year. The contrast between the objective of achieving universal coverage for AIDS treatment and preventing only two out of three new HIV infections is stark. A new president has an opportunity to push beyond PEPFAR by putting prevention on at least an equal footing with treatment. We suggest he declare a specific prevention goal as a *proportion* of total HIV infections rather than as an absolute number of infections averted. For example, he might propose that 90 percent of all HIV infections be prevented in the focus countries by 2016.

In order to provide evidence to Congress of the attainment of the percentage prevention goal, US program staff would first have to work with other donors and the national government in each country to greatly improve existing estimates of the number of annual HIV infections. This effort would serve as the impetus for gathering the epidemiological data to discern where and among whom HIV infections are spreading most rapidly, which is the first step of any successful prevention campaign. As the Institute of Medicine points out in its recent assessment of PEPFAR's implementation, PEPFAR has never done the basic survey work that would be required to monitor its own progress on prevention (Institute of Medicine 2007). In the words of the IOM report, "PEPFAR and other US government-funded programs before it have supported the collection, analysis and appropriate application of both sentinel and behavioral surveillance data in many of the focus countries. ... However, only a few of the countries have conducted behavioral surveys focused specifically on high-risk populations. Without behavioral data on these populations it is difficult for countries and donors to know what specific factors are driving each epidemic and what particular interventions would be the most successful for each country in preventing further spread of HIV." (Institute of Medicine 2007) p. 133)

There are a variety of techniques for reaching high-risk populations with the needed "C" interventions, which promote and distribute condoms and train people in their effective use. Unfortunately few of these techniques benefit from the rigorous impact evaluation that has been exercised on treatment interventions (Wegbreit et al. 2006, 20:1217-1235). The great success of the 100 percent condom program in Thailand in the 1980s was predicated on the existence of brothels which were active and easily identifiable foci for an effective prevention campaign. (Ainsworth and Over 1997) A technique called the "PLACE Method" was developed in the last ten years to achieve the same objective in African epidemiological contexts (Weir et al. 2002, 78 Suppl 1:i106-i113;Weir et al. 2003, 17:895-903;Weir et al. 2004, 80 Suppl 2:ii63-ii68). The method uses interviewers' contacts with taxi drivers, market women and other people in the street to identify the so-called "hot spots" in the town, where people gather to look for a date. Although the formative research to develop this technique and field test it in a dozen African cities was funded by USAID, neither that agency nor PEPFAR has attempted to evaluate the method using rigorous impact evaluation methods or scale up its implementation in order to saturate all or any region of any African country with prevention messages and condoms.

PEPFAR's third report to Congress features its success at expanding three other prevention activities, prevention of transmission from mother to children, blood safety and clean injections. However, since sexual transmission accounts for 80 to 90 percent of all infections in Africa, these seem like Pyrrhic victories (Institute of Medicine 2007) p. 137.

#### III. Meeting our existing commitments

If the US is to maintain and enhance its reputation as an international leader in the area of AIDS funding, it must first keep up with the growing need for treatment and then consider strengthening its AIDS assistance program. Continuing to lead will require greatly increased expenditure and recognition that AIDS treatment expenditures will increasingly be viewed as an "international entitlement".

The term "entitlement" applies to a government expenditure program which engenders the expectation that current beneficiaries will continue to receive funding in future years. The expectation is created partly by the language of the authorizing legislation, which typically endows beneficiaries with the "right" to a continued flow of payments, and partly by the perception that the beneficiaries are vitally dependent on continuation of the funding. The domestic US program that is most commonly described as an "entitlement" program is Social Security, any reduction of which entails a grave reputational and political risk for the politicians who propose it. Since the beneficiaries of PEPFAR's treatment component are foreign nationals, they are endowed legally with neither the right to continued funding nor the right to vote against US politicians who would reduce their benefits. Nevertheless, because these beneficiaries are vitally dependent on continued receipt of AIDS treatment and linked to an international network of articulate AIDS treatment advocates, any withdrawal of treatment funding which threatens their lives will expose the governments of the US and other donor countries to reputational risk at home and abroad and may threaten US politicians at the ballot box.

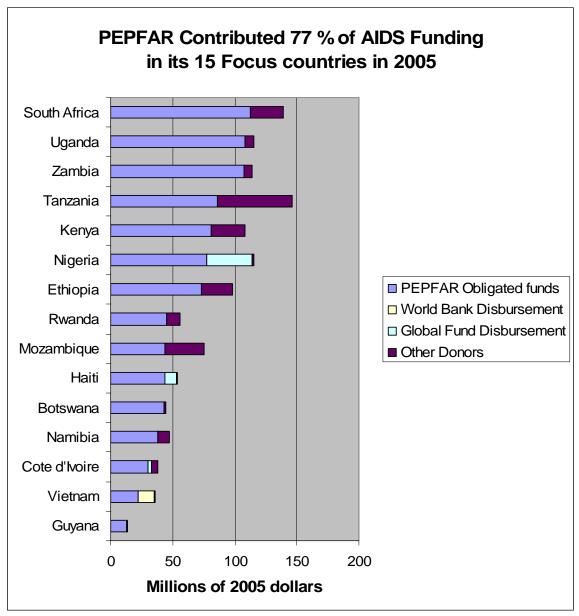
To the extent that the US is providing less than the entirety of AIDS treatment support in each of the 15 countries, the responsibility for any perceived entitlement might be shared with the other donors, reducing the reputation risk to the US. Figure 7 breaks out total external 2005 AIDS funding in the 15 PEPFAR focus countries between PEPFAR and all other donors. Across all 15 countries PEPFAR provided 77 % of declared external AIDS funding in 2005. While we don't know how this figure has evolved in all countries since 2005, in depth study of three of these countries shows that PEPFAR's share has increased rather than decreased. According to Oomman et al., "The large majority of increases [in AIDS funding] since 2004, when spending began to rise most rapidly, can be attributed to PEPFAR alone. By 2006, PEPFAR money constituted 62 percent of HIV/AIDS resources in Zambia, 78 percent in Uganda and 78 percent in Mozambique." (Oomman, Bernstein, and Rosenzweig 2007a) In general, by carrying an average of more than three-quarters of the total external AIDS funding burden and presumably at least as large a

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<sup>&</sup>lt;sup>17</sup> Among the 15 PEPFAR countries, South Africa is the only one to fund a sizable share of the costs of its AIDS interventions from its own budget.

share of treatment spending, these AIDS treatment entitlements are incumbent upon the United States more than on any other donor or group of donors.



(Source: Author's calculations based on data received from the three major donors and from the OECD database)

Figure 7. 2005 AIDS assistance received by 15 PEPFAR countries by donor (Countries ranked by amount of PEPFAR 2005 spending)

### A. The number of new HIV cases is growing faster than the number of people on treatment

The PEPFAR countries achieved extraordinary progress in increasing the numbers on treatment from a few hundred to 800,000 by 2006. On average these countries were able to roll out treatment to almost one fifth of those who needed treatment in those countries each year. Figure 8 shows the projected future growth of people on treatment in the 15 PEPFAR countries under two scale-up assumptions, continued expansion at the historical rate of about 18 percent of unmet need each year and an acceleration to cover 95 percent of unmet need each year. The left panel in the figure shows that even if the historical rate of increase continues, the number with unmet need for treatment in these countries, represented by the dotted green line, continues to increase until about 2012. At that point, given the assumption that the rate of new cases of HIV infection declines steadily at 5 percent a year, unmet need would finally begin to fall. Under this scenario of historical expansion, the number on AIDS treatment in the focus countries will go from about 1.7 million at the beginning of the next president's term to about 3.5 million by the time of the next presidential election. And by 2016, at the end of a possible second term, the number on treatment would be up to 5.4 million. <sup>18</sup>

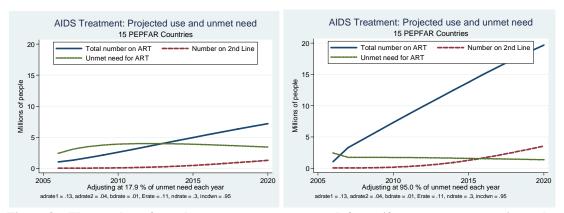


Figure 8. The number of people on treatment grows much faster if access to treatment is accelerated. Panel A: Historical uptake at 17.9 % of unmet need each year, Panel B: Aggressive uptake at 95 % of unmet need each year

But suppose that PEPFAR meets the demand to expand access much more rapidly, covering 95 percent of all unmet need in each future year. The right panel in the figure shows that this rate of expansion would dramatically reduce the unmet need for treatment (the dotted green line turns down and approaches the horizontal axis). Of course the number on treatment rises much more rapidly and many more premature deaths would be averted. Under the same assumption regarding new HIV infections, the PEPFAR countries will have about 4.6 million people under treatment in November 2008 rising to 10 million in 2012 and 15 million in 2016. In these 15 countries, most of these people will be able to thank the United States for their survival – or blame it if the program falters.

### B. Costs will rise dramatically, especially if PEPFAR expands to meet most of the unmet need for AIDS treatment

Growth in US funded treatment implies growth in costs. Figure 9 shows the cost expansion associated with the two scenarios depicted in the previous figure. The solid blue line represents the expanding cost of the treatment component of the PEPFAR program, which rises in the left panel from about one 1.1 billion 2006 dollars a year in 2008 to 2.4 billion in 2012 and 4.5 billion in 2016. The entire US budget for overseas development assistance was \$23 billion dollars in 2006. So if treatment is scaled up in these 15 countries at

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<sup>&</sup>lt;sup>18</sup> See Annex A for details on the model used to make these projections and Annex B for the numerical projections for Figures 9 and 12. Model assumptions are based on (White 2007).

this historical rate, by 2016 the US will have either increased its total overseas development assistance by 20 percent in order to sustain the AIDS treatment entitlement or it will have reallocated about a fifth of its budget to that use.<sup>19</sup>

Under this historical rate of expansion, the extra money that would be required to treat unmet need in any year, called the "funding gap" in the figure, rises from 1.8 billion in 2008 to 2.1 billion in 2012 and then falls to 1.9 billion in 2016. By this measure the US will only be funding about 40 percent of the need for ART treatment in 2008 rising to 70 percent by 2016. The dashed red line shows the portion of total costs which must be spent on the small number of people on second-line therapy. Because the cost per patient is larger for those on second-line, and they steadily accumulate over time, total cost of second-line treatment grows faster than does the number of people on treatment.

The right panel of Figure 9 shows how much faster AIDS spending will increase if the next president accelerates US support to cover 95 percent of unmet need each year. From 2.5 billion 2006 dollars a year in 2008, expenditure would rise to 6 billion in 2012 and then to 11.6 billion in 2016. Thus, to achieve this faster scale-up of treatment through 2016, the country must either increase its total foreign assistance by roughly 50 percent or it must reallocate half its assistance budget to AIDS spending. In this rapid-scale-up scenario, AIDS treatment entitlements will consume somewhere between one third and one half of all development assistance.<sup>20</sup>

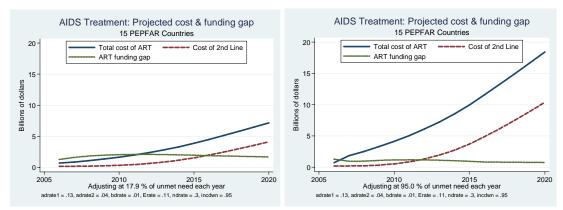


Figure 9. The cost of AIDS treatment grows even faster than the number of treated especially if access to treatment is accelerated. Panel A: Historical uptake at 17.9 % of unmet need each year, Panel B: Aggressive uptake at 95 % of unmet need each year

### C. Successfully treated patients accumulate over time and have an entitlement to more treatment

Although called an "emergency plan," PEPFAR will endure longer than most emergency programs and, unless the US either abandons or hands over its patients to other funders, is likely to persist longer than most foreign assistance projects. As the Economist has pointed out,

"The problem with AIDS is that the more successful you are at treating it, the more you end up paying. That is because, unlike malaria and tuberculosis, it is incurable. Once someone is infected with HIV, the virus that causes it, they will end up requiring treatment for life. Good news for drugmakers, but bad news for both the poor who make up the overwhelming majority of the 40m

<sup>&</sup>lt;sup>19</sup> Calculated as 4.5 billion divided by 23 billion.

<sup>&</sup>lt;sup>20</sup> These projections rely on many assumptions, most of which are detailed in Annex A. Among these is the assumption that unit costs remain constant over time. A brief discussion on this point is presented in paragraph IV.A.

people infected and for the taxpayers of the rich world who will be expected to find much of the money" (The Economist 2007)

Those people whose lives currently are sustained by donor funding of their AIDS treatment may feel that they are entitled to continuation of that treatment, that their donor has entered into an implicit contract to provide life-sustaining drugs in exchange for their conscientious adherence. Furthermore, international and domestic opinion will hold donors responsible for maintaining treatment subsidies to individuals who have already started treatment. As the largest national donor, the US will be seen as particularly accountable for sustaining this life-giving therapy, especially in the 15 PEPFAR countries.

Discretionary spending is whatever is left in a budget after entitlements are funded. From the donors' perspective, the downside of growing entitlements - in the absence of a very large increase in the total aid budget - is that the proportion of discretionary spending in donors' AIDS budgets will decline as donors place more and more patients on treatment. From the recipients' side, the downside of entitlements is dependency. Those who receive entitlements typically become dependent on them, and never more starkly than in the case of expensive life-giving drugs. There may be medium- and long-term negative repercussions from the extreme form of aid dependency that AIDS treatment represents.

Figure 10 projects the proportion of annual AIDS treatment expenditure that will be considered "entitlement" as coverage expands in both the historical and the ambitious expansion scenarios. In both scenarios, the percentage of total expenditure needed by continuing patients grows inexorably over time. That percentage starts lower in the more ambitious expansion scenario, because continuing patients represent a smaller portion of total expenditure.<sup>21</sup>

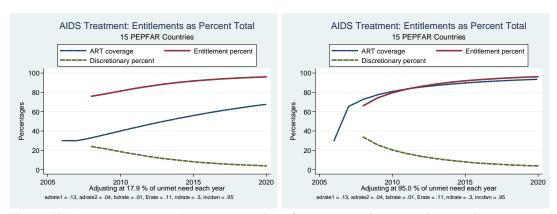


Figure 10. As coverage expands, the proportion of total expenditure that is an entitlement to existing AIDS patients also grows. Panel A: Historical uptake at 17.9 % of unmet need each year, Panel B: Aggressive uptake at 95 % of unmet need each year

Because support for AIDS treatment converts foreign assistance from discretionary to entitlement spending, past treatment expenditure has already locked the US and the rest of the donor countries into a new aid paradigm. Advocates point to the unmet need for care and call for ever-increasing funding levels.<sup>22</sup> To the extent that the international community heeds the advocates' call for more resources, entitlement spending will greatly increase in the next few years. The increase will be both absolute and, unless total assistance expands at the same phenomenal rate, relative to total assistance.

<sup>&</sup>lt;sup>21</sup> Whether expansion to the new patients is considered "discretionary," as it is termed in the graph's legend, is ultimately a political decision. The suggestion is that the moral imperative to treat will be particularly strong for existing patients, who will be deemed to have an "entitlement", whereas new patients might, at least in theory, find other sources of support.

<sup>&</sup>lt;sup>22</sup> On September 26, 2007, UNAIDS published "Financial Resources required to Achieve Universal Access to HIV Prevention, Treatment, Care and Support" to request \$50 billion a year in AIDS funding – up from the current level of about \$10 billion a year.

Are voting taxpayers of the US and other OECD countries ready for this new entitlement paradigm? Growing funding for AIDS treatment suggests this possibility. But there is reason for concern. Historically when budgets expand less quickly than planned, growing entitlements often squeeze out discretionary programs. In comparison to the moral imperative to continue funding AIDS treatment, HIV prevention all other assistance programs will appear to be discretionary. So if the requested additional AIDS funds are not forthcoming, the discretionary assistance will be squeezed out. By one calculation, the \$50 billion a year requested by UNAIDS from all donors to meet "universal access" objectives for treatment and prevention could squeeze out spending on all eight of the United Nations Millennium Development Goals.<sup>23</sup>

#### IV. Reputation risks lie ahead

While reneging on entitlements would certainly be a reputation risk for the next president, maintaining AIDS treatment entitlements, or even scaling them up at current rates of increase, difficult and expensive as that will be, will not suffice to avoid such risks.

### A. Scaling up requires extending high quality treatment to less accessible populations

The cost projections in Figure 9 above assume constant average costs. This may seem to be a pessimistic assumption in view of the rapid decreases in drug costs that have occurred during the last decade. However, any future decreases in drug cost may be offset by the increased cost per patient necessary to scale up to reach full coverage targets. If the smallpox eradication program is a guide, reaching the last people with AIDS treatment may cost hundreds of time more per patient-year of extended life than reaching the first 25 percent. Furthermore, these cost projections do not consider the future demand for third-line and so-called "salvage" medications by those who fail second-line therapy. These medications are even more costly than the second-line therapies considered here.

Additionally, as shown in Figure 12, disinhibition could increase costs by as much as an additional 20 percent by substantially increasing the number of new people affected by HIV. So on balance it seems inconsistent to assume both rapid scale-up and continued decline in unit costs.

### B. Strong treatment programs may foster complacency and resentment in recipient countries

One potential risk from the AIDS component of the US foreign assistance program to the reputations of the next president and of the United States is that the benefits in terms of freely accessible AIDS treatment will be offset by a relaxation of prevention efforts or a "disinhibition" of risky sexual behavior.<sup>24</sup> A more subtle but potentially more insidiously dangerous risk is that the unusually strong dependency created by US funding of AIDS treatment may undermine the relationship between the US and recipient countries.

### 1. Complacency is an understandable and even "rational" response to free and accessible AIDS treatment

As yet there is little evidence of the effect of AIDS treatment on risk behavior of those at most risk of infection. There is accumulating evidence to show that treatment availability encourages people to find out their own infection status. But increased testing in response to treatment accessibility has not been convincingly shown to reduce high risk behavior among the HIV negative. Indeed it may do the opposite depending on the knowledge and education of the individual.<sup>25</sup>

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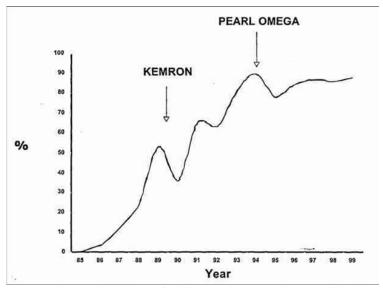
<sup>&</sup>lt;sup>23</sup> A 2002 World Bank study (Devarajan, Miller, and Swanson 2002, no. 2819) in support of the UN-mandated Millennium Development Goals estimated that the cost of achieving all eight of the goals by the year 2015 would be between \$40 and \$60 billion dollars a year.

<sup>24</sup> One of the first uses of the term disinhibition was in two publications reporting a modeling study of the

One of the first uses of the term disinhibition was in two publications reporting a modeling study of the impact of AIDS treatment on India. (Over et al. 2006, 33:S145-S152;Over et al. 2004) Also see (Cassell et al. 2006, 332:605-607).

<sup>&</sup>lt;sup>25</sup> See Section IVC of this paper.

Visits to treatment centers in Africa turn up stories which illustrate the potentially perverse effect of free and effective AIDS treatment. For example, on a visit to a well-functioning AIDS treatment clinic in South Africa, a social worker cited the case of a woman who had asked for him to reveal which of the men was HIV positive – so that she could get infected from him and share in the disability payments and free food available to HIV-infected people in South Africa. Until more data is collected and analyzed, it is hard to know if such stories are representative of broader trends or are only rare and isolated regrettable cases. However, Figure 11 shows disturbing data from a cohort of Nairobi sex workers collected for more than a decade by a research team including researchers from the University of Manitoba. Is it only a coincidence that efforts to promote condom use suffered severe set backs each time the press announced a supposed "cure" for AIDS? In the absence of more information, causality is hard to determine. But if news of a false cure, though expensive and hard to obtain, could persuade prostitutes to reduce condom use by almost 20 percent, what impact will a widely accessible and highly effective treatment have on risk behavior? The properties of the pro



Source: Jha et al., 2002, as cited in (Over, Heywood, Marseille, Gupta, Hira, Nagelkerke, and Rao 2004) Figure 11. The announcement of false "cures" for AIDS in 1989 and 1994 apparently caused substantial reductions in condom use in a cohort of Nairobi prostitutes.

Panels A and B of Figure 12 repeat the projections of Panels A and B of Figure 9 with one difference. Instead of declining at 5 percent a year, the annual rate of new infections (or, in epidemiologists' parlance, the incidence rate), increases by 15 percent each year. With historical uptake, the ART funding gap never turns down as it did in Panel A of figure 6. With aggressive uptake, total expenditure reaches 25 billion a year instead of 18 billion a year at the end of the period.

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<sup>&</sup>lt;sup>26</sup> Preliminary analysis of cross-section survey results from Burkina-Faso and Ghana, done jointly with Damien de Walque and Harounan Kazianga of the World Bank, suggests that knowledge of the availability and effectiveness of AIDS treatment leads to extra marital sex for married individuals, but also leads to more condom use on these contacts. If these findings are borne out by detailed analysis, the question will arise whether the net effect of these two offsetting influences is to increase or decrease HIV transmission.
<sup>27</sup> In an op-ed piece in the Baltimore Sun, Michael Klag, the dean of the Johns Hopkins School of Pulbic Health calls for PEPFAR to fund "research to investigate the effect of PEPFAR's HIV therapy on the spread of HIV and on drug resistance ... ". (Klag 2007).

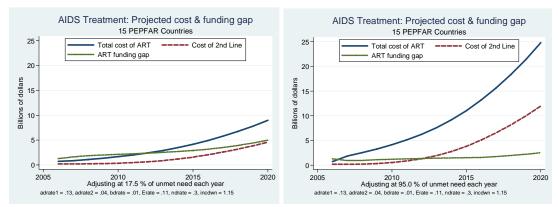


Figure 12. If AIDS treatment disinhibits risk behavior, costs will grow even more rapidly. Panel A: Historical uptake at 17.5 % of unmet need each year, Panel B: Aggressive uptake at 95 % of unmet need each year.

#### 2. Entitlements might engender complacency and resentment

To the extent that AIDS treatment is viewed as an entitlement by all parties to the transaction, the donor governments and their citizens on the one hand and the recipient governments and their patients on the other, the recipient governments and individuals might have diminished incentives to prevent HIV infection or to use efficiently the externally provided resources. Furthermore, it is human nature for people who are dependent on others to resent the dependency relationship.

In the extreme, it is possible that a strong AIDS program in these 15 countries will create a kind of post-modern colonial relationship between the US and these countries – undermining the quality of these bilateral relationships. To take just one example, suppose the US wishes a country to relinquish its rights under the WTO TRIPS agreement. If millions of that country's citizens are dependent on the US to fund their life-sustaining AIDS treatment, this will increase the US bargaining power on this bilateral trade negotiation – and engender resentment among the government officials and the citizens of the recipient country.

#### C. Individual HIV testing may aggravate the epidemic

Originally HIV testing policies in developing countries were guided and circumscribed by the overriding ethical imperative to protect the emotional well-being and the confidentiality of tested individuals, leading to the policy of "voluntary counseling and testing" or VCT. This approach made sense in rich countries where prevalence rates in the general population were under one percent and HIV infected people were likely to be stigmatized either as homosexuals or drug users. The epidemic's danger to public health was small and the potential danger to the individual from stigmatization was large. However, in the worst affected countries today the situation is reversed. With up to 30 percent of the population infected, the danger to the public health is astronomical. At the same time the danger of stigmatization, while still present, is receding day by day. And many of those who test positive can immediately be offered effective treatment in PEPFAR's focus countries. In response to this changed perception of costs and benefits, first Botswana and then other countries have shifted from the human-rights guided policy of individual-initiated "voluntary" counseling and testing for HIV to a public-health-guided policy called "provider initiated testing", with little or no counseling for the majority who are HIV negative. This change seems to be supported by the Botswana public (Weiser et al. 2006, 3:e261). <sup>28</sup> Table 2 shows that this policy change has now occurred in most of the PEPFAR countries.

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 $<sup>^{28}</sup>$  Although the case for this policy is not as strong in the US, the Center for Disease control has recommended a shift to "opt-out" testing domestically as well (Holtgrave 2007, 4:e194).

There is widespread and convincing anecdotal evidence that the shift to provider-initiated (or "opt-out") testing has speeded the recruitment into AIDS treatment of patients who might otherwise have waited too long before seeking treatment on their own. This policy shift is therefore almost certainly contributing to treatment success.

However evidence is accumulating that expanded *individual* HIV testing is an imperfect prevention intervention. Many individuals who learn their HIV status seem to react by maintaining or even increasing their risk behavior. For example, a review of 50 studies conducted in 1991 found mixed effects of voluntary counseling and testing (Higgins et al. 1991, 266:2419-2429). Recent studies in the Rakai region of Uganda have found "no impact of VCT on subsequent risk behaviors or incidence" (Matovu et al. 2005, 19:503-511).

Table 2. Date of adoption of provider-initiated HIV testing in 15 PEPFAR focus countries

Date of policy				
Country		adoption		
Botswan	а	2003		
Côte d'Iv	oire	-		
Ethiopia		-		
Guyana		2006	1	
Haiti		-		
Kenya		2004		
Mozamb	ique	-		
Namibia		2004	2	
Nigeria		-		
Rwanda		2006		
South Af	rica	-		
Tanzania	a	2006		
Uganda		2005		
Vietnam		2006		
Zambia		2005	3	
1 Guyana's p	rovider-initiate	d testing policy is for labor and		
delivery ward	s only.			
· ·		ed testing policy is for PMTCT,		
ANC and TR	only and inclu	dee provision for non-laboratory		

ANC, and TB only and includes provision for non-laboratory personnel including community counselors to perform rapid HIV testing

Source: Table 7 of (OGAC 2007)

Furthermore, those who have received multiple negative HIV tests (such as occurs with provider-initiated testing at every visit to a health center) were more likely to have more than two sexual partners and to use condoms inconsistently (Matovu et al. 2007, 11:71-78). If this finding is replicated elsewhere, the expansion of provider-initiated testing driven by the availability of AIDS treatment might have the perverse

<sup>3</sup> Zambia adopted a PMTCT-specific provider-initiated testing policy in 2004.

<sup>&</sup>lt;sup>29</sup> This result was predicted by economists based on the observation that confidential individual testing increases the asymmetry of information between the tested person and everyone else (Over 1999, 3rd;Philipson and Posner 1993). People tend to take advantage of privileged information in their business transactions (e.g. insider trading scandals on Wall Street). If a similar tendency in sexual transactions is not completely restrained by altruism, people who learn they are HIV positive may increase their risk behavior on the grounds that they have nothing to lose. On the other hand, people who have previously taken risks and learn they are HIV negative may falsely conclude that they are immune to infection and hence take even more risks (Thornton 2005).

effect of accelerating the epidemic. <sup>30</sup> Thus, it appears that a further more dramatic policy shift may be required, such as introducing and expanding couples-testing. This policy option is discussed below.

#### D. Expanding AIDS treatment may crowd out other health care

The extraordinary expansion of AIDS treatment currently underway in the worst affected countries is putting pressure on the supplies of all the factors of health care production, from nurses and doctors to health care facilities. There is currently a debate between those who believe that such pressures will undermine the health systems in these countries and those who maintain that improving AIDS care will have beneficial spillover effects on the rest of health care in these countries.

How much pressure will the worst-affected countries actually experience? In order to understand the pressure that AIDS treatment will bring to bear on a country, it's necessary to relate the total amount of care needed to the supply of health care resources.<sup>31</sup> One easy way to do that is to construct a ratio between the two. Figure 13 presents the distribution of this ratio of need per physician for all the AIDS affected countries in the world.

<sup>&</sup>lt;sup>30</sup> Suppose that adults at risk of HIV infection are not all equally motivated by a desire to protect their sexual partners from infection, but all are equally motivated by a self-interested drive to avoid their own deaths from AIDS. Those who are most altruistic would have been motivated to learn their own infection status even in the absence of effective AIDS treatment. As news spreads of the accessibility of effective treatment, a surge in demand for testing will come disproportionately from those who would not have sought testing only to protect others. If condom use is even slightly inconvenient or unpleasant, more self-interested people will respond to the information that they are HIV positive by reducing their condom use rather than increasing it. Under this set of plausible conditions, accessible AIDS treatment accelerates HIV testing by differentially recruiting those who are most likely to use the knowledge they are infected in a socially irresponsible way. Thus it is inescapably plausible that the expansion of AIDS testing in the presence of effective AIDS treatment will accelerate the spread of HIV.

<sup>31</sup> An alternative approach would be to relate the cost of treating AIDS patients to total national health

<sup>&</sup>lt;sup>31</sup> An alternative approach would be to relate the cost of treating AIDS patients to total national health expenditure. However, this approach amounts to assuming that the total consumption of care is a good index of the available supply, an unreasonable assumption when physicians are over-worked in some countries and unemployed in others.

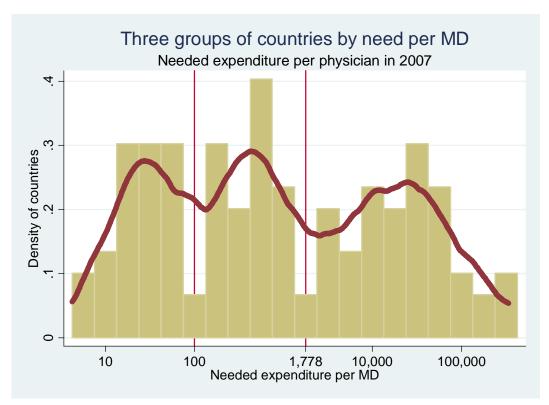
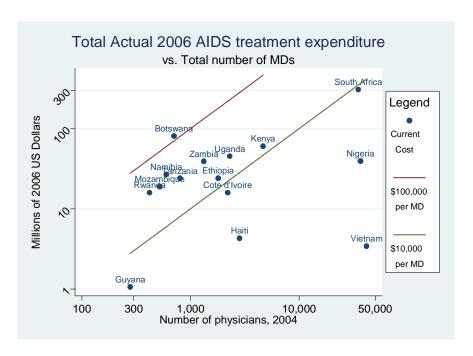


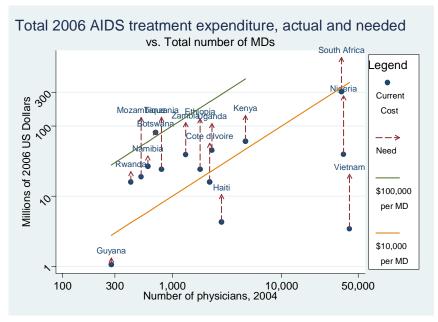
Figure 13. Distribution of needed AIDS treatment expenditure per physician

The distribution has three peaks and thus allows grouping the countries into three groups, according to the needed expenditure per physician in US dollars. The group of countries on the right of the distribution, with need per physician larger than \$1,778, will experience the most pressure. This is the part of the distribution which is inhabited by most of the 15 PEPFAR countries.

Figure 14 displays estimated current expenditure for the 15 PEPFAR countries plotted against the number of MDs in each country. Diagonal lines are drawn for equal burdens per physician of \$100,000 (the red line) and \$10,000 (the green line). Botswana's health system must absorb the largest burden per physician as shown by its position to the northwest of the red diagonal. Figure 15 superimposes the estimated need for AIDS expenditures on top of the estimated current expenditure. The arrow connecting the two is longer when need is a large multiple of current treatment. Note that if Mozambique and Tanzania succeed in making ART available to all, their health systems must join Botswana's in absorbing more than \$100,000 per MD.



Source: Author's calculations with WHO data on numbers of physicians in 2004, the latest year available. Figure 14. Estimated current AIDS expenditure is more than \$10,000 per physician for 9 of the 15 PEPFAR countries



Source: Author's calculations with WHO data on numbers of physicians in 2004, the latest year available Figure 15. Needed AIDS expenditure is more than \$100,000 per physician in Mozambique, Botswana and Tanzania

If the PEPFAR program succeeds in expanding treatment to meet the need, each country will move up its arrow in Figure 15 and each of the physicians working in AIDS will have to manage the very large amounts of health care resources represented by the those arrows. Without changes in technology, this calculation suggests extreme stress on the health care systems of the worst affected countries. Some of the symptoms of this stress could be expected to be: physicians and nursed pulled out of non-AIDS care to focus

exclusively on AIDS, reduced quality of care as individual physicians spread themselves too thinly, poor absorptive capacity of the health systems as doctors are unable to supervise such large quantities of resources, increased leakage in the form of waste or corruption. All of these possibilities pose reputation risks for the donors viewed to be "at fault" (Piller and Smith 2007).

However, the situation is complicated by our inability to predict the future progression of the number of physicians in each country or the extent to which physicians will increase their "span of control" by supervising larger numbers of intermediate level health care personnel. Will the excess demand for the labor of health care specialists pull more of the country's brightest students into AIDS treatment (Clemens and Bazzi 2007)? If so, the dots representing the countries in Figure 12 will migrate towards the right as well as upward and the burden per physician will be smaller. Will AIDS funding be accompanied with funding for the rest of the health care system so that patients with other health problems also benefit (Price et al. 2007)? If so, then the extraordinary increase of disease specific funding will have few pernicious effects on the health system.

On the other hand, if health care personnel leave these countries in search of better wages faster than more can be trained, then the burden will be larger (Barnighausen, Bloom, and Humair 2007). More research is needed to understand how severely these countries are burdened by the effort to treat all AIDS patients while maintaining their services to other patients.

#### V. From an emergency plan to a sustainable policy

Foreign assistance can be classified into four types, which have different objectives and different justifications. Emergency relief and redistributive welfare programs are intended to extend a helping hand to our unfortunate neighbors out of empathy, because "there but for the grace of God go I". Military assistance is offered sometimes out of empathy for the plight of another people, but more often to bolster the national security and further the strategic interests of the donor country. Development programs and projects constitute the fourth category, which is intended to stimulate the economic growth of the recipient country on the grounds that "it is better to teach a man to fish than to give him a fish every day".

While there is a growing literature on the investment benefits of programs to combat AIDS, there is only weak support for the proposition that subsidized AIDS treatment for the poorest AIDS patients will stimulate national growth – except in the health sector where it is rumored to have substantially augmented doctors' incomes. The attempts to expand US support for AIDS treatment during the Clinton administration were justified on national security grounds. An innovation of the Bush presidency was to largely eschew national security as a justification for the PEPFAR program. Instead the Bush administration used the AIDS program as the prime international exhibit for its vaunted philosophy of "compassionate conservatism". As its name signifies, PEPFAR was originally justified primarily as an emergency plan. However, the fact that it is creating entitlements which most recipient countries could not shoulder and is hard to justify on investment grounds suggests that it is really an international transfer program, comparable perhaps to US food assistance. Programs to redistribute resources from the US taxpayers to the poor in developing countries constitute state supported international welfare programs.

Our recommendations to the next president are grouped under three headings: manage the AIDS treatment entitlement, prevent the future need for treatment and assure the "AIDS transition".

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<sup>&</sup>lt;sup>32</sup> The US constituency for US food aid is a coalition between supporters of altruistic aid to hungry people in developing countries and US farmers who benefit when the US buys the food to be donated overseas. The US constituency for the PEPFAR program has analogously consisted of a coalition between supporters of altruistic treatment for AIDS patients and US multinational pharmaceutical manufacturers who benefit when the US buys their products for donation overseas. The recent shift of US policy towards approval of the purchase of generic drugs from non-American sources weakens but does not completely vitiate this analogy.

#### A. Manage the AIDS treatment entitlement

In order to make space in the AIDS budget for HIV prevention spending, which is the only existing technology for reducing the need for treatment, and to avoid the reputation risk of failed support for AIDS treatment, the next President must wisely manage the treatment entitlements that he or she inherits from the current administration.

#### 1. Maximize success of ongoing treatment

As an assistance program expands and matures, it can become encumbered by leakages and inefficiencies. In the case of AIDS treatment, these problems would mean loss of patient life, increased resort to second-line therapies and the consequent expense and increased transmission of drug-resistant strains of HIV. To prevent US-funded AIDS treatment in the focus countries from suffering this fate, the US must assure the effective supervision of AIDS treatment personnel and supplies in the 15 countries. Furthermore, the US should provide small start-up funds for the formation of patient-managed adherence support organizations. Such groups would help slow the development of drug resistance not only for antiretroviral medications but for medications against malaria and TB and even for antibiotics. Such demand-side mechanisms can help assure quality treatment in the private sector, where command and control supervision doesn't reach.

#### 2. Reduce unit costs of treatment

While the continuing drive to extend treatment to almost all who need it will drive up unit costs, US support for AIDS interventions should work to bring down unit costs in other ways. The new president should actively collaborate with WHO's program to certify generic versions of antiretrovirals for use in PEPFAR countries and should cooperate with the Clinton Foundation's efforts to lower drug prices through long-term contracts for large quantities. As a last resort when patent holders fail to "sufficiently" reduce their prices for poor countries, the US should support compulsory licensing of AIDS drugs by poor countries and by third-party countries such as Canada which can then export to poor countries. The US should cease using bilateral trade agreements to constrain the use of compulsory licenses for treating diseases that are specific to poor countries (Fink and Elliot 2007).

#### 3. Limit the expansion of AIDS treatment entitlements

In view of the reputational risk to the US of AIDS treatment entitlements, the new president should moderate the expansion of treatment entitlements to new beneficiaries while at the same time he or she upholds and even strengthens existing ones. Several strategies for limiting the imprudent expansion of entitlements are available. First, the president should resist the pressure to expand the number of focus countries targeted by PEPFAR. This group of countries already accounts for almost half of existing AIDS cases and more than half of new cases worldwide. The US should concentrate on doing a good job in these countries at least through the next two presidential terms, leaving the rest of the donor countries, the Global Fund and other mechanisms to deal with the other countries.<sup>34</sup> If the US does a good job in these countries,

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<sup>&</sup>lt;sup>33</sup> Such organizations can include tuberculosis patients, because HIV positive patients more easily contract TB and can spread it to people regardless of their HIV status, adherence to TB medication is an important public health issue whether or not one has AIDS and inclusion of TB patients in the group might reduce the stigma on AIDS patients. To the author's knowledge, no such group has been subjected to rigorous impact evaluation, which is urgently needed. The potential cost-effectiveness of such groups has been estimated for Thailand (Over, Revenga, Masaki, Peerapatanapokin, Gold, Tangcharoensathien, and Thanprasertsuk 2007, 21 Suppl 4:S105-S116).

<sup>&</sup>lt;sup>34</sup> Since congress has authorized an increase in the annual funding level of PEPFAR to \$50 billion over the next 5 years, there is discussion of whether to expand the number of focus countries. Proponents of expansion argue that the absorptive capacity of the original 15 countries is limited and may not accommodate such a large increase in funding, while substantial expansion of treatment coverage can be achieved more easily in other countries not currently included, such as Malawi or Lesotho. However, while the goals of universal treatment access and reduced incidence of new cases are far from met in the

spillovers to the other countries will benefit the rest of the world, whereas poor performance in the focus countries will cast a shadow on treatment efforts in other countries. Examples of benefits that would spill over from focus countries to their neighbors include low generic drug prices, lessons about what works in treatment and prevention, reduced stigma for AIDS patients and safer norms of sexual behavior.

### **Box 2.** A promising technical option for fulfilling PEPFAR's original goal to provide palliative care by Mead Over, Stuart Grossman, and Julette-Marie F. Batara

Pain is a common and devastating complication of AIDS, cancer, and many other life threatening illnesses. Adequate control of pain is of utmost importance to patients with terminal illnesses and their loved ones. Pain relief diminishes the stigma with which sick people might otherwise be regarded(Harding et al. 2003, 3:33). In addition, it frees both the patient and the patient's supporters to focus on their overarching challenges, such as maximizing the effectiveness of treatment, maintaining the functions of the household or, in cases where treatment has failed, coming to terms peacefully with end-of-life issues such as leave-taking and inheritance.

Unfortunately effective pain management medications are largely unavailable to most health care providers in the developing world, especially in Africa (Foley et al. 2008, 2nd:981-994;Harding et al. 2005, 40:491-492;Harding and Higginson 2005, 365:1971-1977;Rhodes and Grossman 1997, 14:535-542). The governments and donors responsible for pharmaceutical purchases in poor countries have been unable to overcome the obstacles raised by limited funding for pain management agents, the desire to direct those agents to children and adults with good prognoses, concerns regarding drug storage and compliance, and concerns regarding drug diversion. (Koshy et al. 1998, 6:430-437)

In recognition of its importance, the original PEPFAR legislation specifically mentions pain management among the services which are mandated to receive fifteen percent of total PEPFAR funding in each country (Institute of Medicine 2007). PEPFAR has a "Palliative Care Technical Working Group" to advise the program on how to spend this money. However, the fact that the Working Group's 2006 objectives only included (1) tools "to ascertain [the] severity of symptoms and pain related to HIV disease" and (2) "support for the development of template/curricula for pain/symptom management" (ibid, p. 195) with no mention of arrangements to purchase and utilize better pain medication suggests that only a small of the fifteen percent actually mitigates pain.

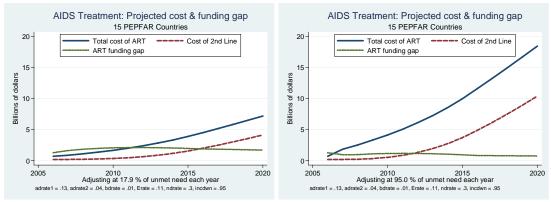
A technical innovation which is close to entering human trials offers the hope of dramatically improving pain relief for cancer and AIDS patients in poor countries. It is designed to bypass the complex issues of compliance and drug storage and to dramatically reduce the risk of drug diversion.

The breakthrough is to construct a small polymeric implant (the size of a shirt button), that contains hydromorphone (a potent morphine derivative in general use in developed countries). This implant will release hydromorphone at a continuous rate for 30 to 90 days. It is implanted just under the skin of the patient with a simple procedure that requires no sutures(Lesser et al. 1996, 65:265-272). By properly matching the geometric construction of the tablet to the pain relief requirements of the patient, it is likely to alleviate most pain for a period of 30 days, when a new tablet can be implanted. Furthermore the production of these implants is straightforward and inexpensive suggesting, that this method of pain relief will be similar in cost to current treatment with morphine.

We recommend that renewal of US support to AIDS treatment and care include explicit provisions for piloting the distribution of pain management medication including these hydromorphone impregnated tablets, which can be prescribed and administered in a controlled setting in each of the fifteen focus countries. Based on the results of these pilot programs, each country could then propose a plan for scaling up the distribution of analgesics, so that no one suffering from extreme pain is deprived of relief.

Limiting expansion of AIDS treatment in the fifteen countries to the rate of increase that PEPFAR has achieved up to now would require the AIDS treatment budget to grow as in panel (a) of Figure 16, to about \$5 billion per year in 2016 and \$7 billion per year in 2020. This rate of expansion saves \$7 a year in 2016

original 15 countries, the US will better manage its entitlements by channeling any funds not usable in those countries through the multilateral AIDS funding agencies – especially the Global Fund.



Source: (Over 2008b)

Figure 16 - The cost of AIDS treatment grows even faster than the number of treated especially if access to treatment is accelerated. Panel A: Historical uptake at 18 % of unmet need each year, Panel B: Aggressive uptake at 95 % of unmet need each year

to \$10 billion per year in 2020 compared to the aggressive uptake scenario in panel (b), money which can be spent on urgently needed HIV prevention and on strengthening the health care systems of the recipient countries.<sup>35</sup>

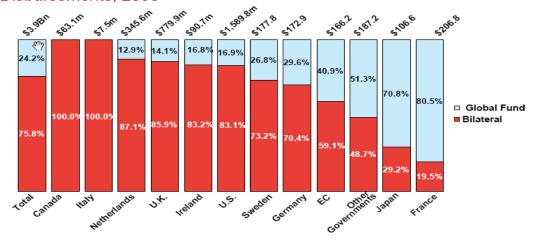
A second strategy open to the president for limiting the growth of US entitlements is to increase the proportion of US-financed AIDS funding that passes through multilateral institutions, including the Global Fund and the World Bank. Not only does this strategy shift the entitlement from the US government to the multilateral, but it can benefit the recipient nations and patients by stimulating competition on the ground among alternative AIDS treatment and prevention institutions. The ongoing HIV/AIDS Monitor project (Center for Global Development 2007), which compares the performance of the three largest AIDS funders in three countries, already shows how recipient countries benefit when the evaluators can compare the funders to one another.

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<sup>&</sup>lt;sup>35</sup> The two right two panels panels of the in the Annex table present for the numerical projections under historical and rapid uptake, assuming incidence declines at 5 percent per year. Over the five year period of the proposed PEPFAR reauthorization, 200910-134, this table predicts that AIDS treatment expenditures will total up to \$25.8 billion dollars. As reported in Box 1, Congress has recently authorized that 80 percent of \$50 billion, or \$40 billion, be spent on AIDS of which more than 20 percent (\$8 billion) should be spent on HIV prevention and another substantial portion on care and support for patients and their orphaned children. Furthermore a large, but unknown proportion of the \$40 billion would flow to the Global Fund for AIDS, TB & Malaria. Thus \$25.8 billion represents up to 25 percent more AIDS treatment expenditure than has yet been authorized. These projections include estimates of the variable cost per patient in each country, but do not include any fixed cost per country or per treatment site. See Over (2008a) for more details on the projections.

### International AIDS Assistance: G8/EC Funding Channels for Disbursements, 2006



Source: (Kates, Izazola, and Lief 2007)

Figure 17. The US should channel more than the current 17 % of AIDS resources through the Global Fund

Figure 17 shows the percentage of AIDS financing that passes through the Global Fund for each of the OECD donors. The US is ranked sixth in the group, passing only about 17 % of its resources through the Global Fund. There is room for substantial expansion here.

#### 4. Support the creation of a Global Health Corps

As the US continues to extend AIDS care in the fifteen PEPFAR countries, the burden on the existing health care systems will grow more and more onerous. From the current levels of more than \$10,000 dollars per physician, expansion will soon require expenditures of up to \$100,000 per physician each year. (See Figure 15.) This additional burden on top of the existing health care needs threatens to divert resources away from patients suffering from other health problems. (Piller and Smith 2007).

While one obvious answer to this problem is for the US to support general health system strengthening like that documented in Rwanda (Price, Micomyiza, Nyeimana, and Tchupo 2007), more is needed. The President should support the creation and deployment of a global Health Corps (Levine 2008). A key feature of this Corps is its offer to fill the most serious gaps in the health care needs of the host country, not just contribute to AIDS treatment. By responding to requests to send American health care personnel to PEPFAR countries, and by bringing selected members of those countries' medical professionals to the US for a year of study, the President will be demonstrating the country's willingness to engage its most valuable resource – its own people in the struggle against the health problems of the PEPFAR countries.

#### B. Prevent the future need for treatment

The old proverb that an ounce of prevention is worth a pound of cure has never been truer than it is now with the AIDS epidemic.<sup>36</sup> The President should propose a dramatic new objective: **prevention of 90 percent of new infections in the focus countries by the year 2012**. Since the current number of new infections each year in the 15 focus countries is about 1.4 million, this goal would commit the US to reducing this number to about 140,000 by the year 2016. Establishment of such a goal recognizes the

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<sup>&</sup>lt;sup>36</sup> This proverb suggests that the benefit to cost ratio of prevention might be 16 to one, but the Thailand calculations cited earlier suggest a ratio of 43 to one. In the AIDS epidemic, an ounce of prevention is worth two and a half pounds of cure.

superior cost-effectiveness of prevention in the long run and commits the country to developing and applying interventions and measurement tools which will advance the prevention agenda and measure its progress. <sup>37</sup>

#### 1. Prevention will eventually save money

Because every new HIV infection adds to the AIDS treatment burden five to ten years later, it is becoming a fiscal imperative to slow the progress of HIV infection. Figure 9 above showed how the treatment burden would grow if HIV infection rates by only five percent each successive year. Figure 18 shows the effects of a more dramatic decline of 90 percent each year. If the US is able to help the 15 focus countries to slow the growth of HIV this much starting in 2008 and the rate of treatment uptake is maintained at 18 percent of unmet need each year, by 2020 the cost of treatment will be smaller by about \$1.4 billion a year – releasing resources for discretionary foreign assistance objectives.<sup>38</sup>

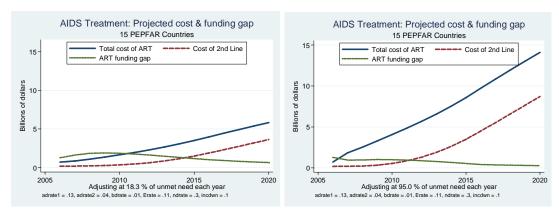


Figure 18 - Cost projection of AIDS treatment in 15 PEPFAR countries if rate of new infections decreases by 90 percent a year. Panel A: Historical uptake, Panel B: Aggressive uptake

The imperative to strengthen HIV prevention programs is reinforced not only by the cost of treatment, but also by the possibility that access to treatment may, itself, speed infection. As pointed out above, free access to widely available and demonstrably effective treatment can engender complacency leading to the disinhibition of risk behavior. Following the Hippocratic injunction to "first, do no harm", the US must strengthen prevention programs at least in focus countries.

A possible unintended consequence of the rapid and effective rollout of ART in PEPFAR focus countries may be to attract immigration from neighboring countries where AIDS treatment is less accessible. Because successful prevention in those neighboring countries will eventually slow that influx of AIDS

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<sup>&</sup>lt;sup>37</sup> This goal is consistent with the President's call to avert 5,000,000 new infections over the next five years. However, calculating averted infections requires estimating the number of infections there would be in the absence of US effort. This is a tricky exercise partly because of the well known difficulties of attributing changes in national indicators to the contributions of any one partner and partly because the same person's infection can be multiplied repeatedly, month after month, year after year. The latter problem means that any estimate of cumulated infections averted exaggerates the number of people helped and can obscure lack of progress in reducing the *rate* of infection. A preferable approach is to set a target for the maximum absolute number of annual new infections which is 90 percent lower than the estimated current level. Note that women, who now bear a disproportionate share of the burden of the epidemic, will reap most of the benefits of a vigorous prevention campaign. Thus there is no need to establish separate objectives regarding prevention among women.

<sup>&</sup>lt;sup>38</sup> This figure is the difference between \$7.18 billion and \$5.83 billion, the figures for 2020 "Total Cost" in the top two panels of Annex B. At rapid uptake the saving in 2020 would be \$4.34 billion, more than twice as large. This figure is the difference between the 2020 "Total Cost" in the bottom two panels of the Annex B.

patients to PEPFAR countries, PEPFAR should especially contribute to prevention programs in countries bordering with PEPFAR countries.

#### 2. Support promising prevention opportunities

Much has been published about prevention strategies, and this is not the place to review all the options. It is depressing and even scandalous that after more than 20 years of donor funded prevention efforts, so few prevention interventions have been rigorously evaluated (Wegbreit, Bertozzi, DeMaria, and Padian 2006, 20:1217-1235). Five neglected prevention strategies that seem both technically and politically feasible, based on current knowledge, deserve particular attention in PEPFAR countries: (i) Improved targeting of prevention efforts in places frequented by those at most risk of contracting and transmitting the infection; (ii) The mobilization for HIV prevention of the people who receive U.S.-funded AIDS treatment; (iii) The expansion of access to male circumcision; (iv) The integration of family planning services with HIV testing and AIDS treatment; (v) The reorientation of HIV testing toward in-home services for couples, rather than facility-based testing of individuals.

#### a) A. Target HIV prevention efforts to hot spots

The first step in a successful prevention campaign is to gather the epidemiological data to discern where and among whom HIV infections are spreading most rapidly. As the Institute of Medicine points out in its recent assessment of PEPFAR's implementation, PEPFAR has never done the basic survey work that would be required to monitor its own progress on prevention (Institute of Medicine 2007). In the words of the IOM report, "PEPFAR and other US government-funded programs before it have supported the collection, analysis and appropriate application of both sentinel and behavioral surveillance data in many of the focus countries. ... However, only a few of the countries have conducted behavioral surveys focused specifically on high-risk populations. Without behavioral data on these populations it is difficult for countries and donors to know what specific factors are driving each epidemic and what particular interventions would be the most successful for each country in preventing further spread of HIV." (Institute of Medicine 2007) p. 133)

There are a variety of techniques for reaching high-risk populations with the needed interventions, which promote and distribute condoms and train people in their effective use. Unfortunately few of these techniques benefit from the rigorous impact evaluation that has been exercised on biomedical prevention techniques or treatment interventions (Wegbreit, Bertozzi, DeMaria, and Padian 2006, 20:1217-1235; (Lagakos and Gable 2008, 358:1543-1545) . The great success of the 100 percent condom program in Thailand in the 1980s was predicated on the existence of brothels which were active and easily identifiable foci for an effective prevention campaign. (Ainsworth and Over 1997) A technique called the "PLACE Method" was developed in the last ten years to achieve the same objective in African epidemiological contexts (Weir et al. 2002, 78 Suppl 1:i106-i113;Weir et al. 2003, 17:895-903;Weir et al. 2004, 80 Suppl 2:ii63-ii68) . The method uses interviewers' contacts with taxi drivers, market women and other people in the street to identify the so-called "hot spots" in the town, where people gather to look for a date. Although the formative research to develop this technique and field test it in a dozen African cities was funded by USAID, neither that agency nor PEPFAR has attempted to evaluate the method using rigorous impact evaluation methods or scale up its implementation in order to saturate all or any region of any African country with prevention messages and condoms.

#### b) Mobilize AIDS patients for HIV prevention

It is easy to misunderstand the intent of this suggestion. Doctors will tell you that they are already counseling their patients in safe-sex and suggest that more effort like this is the kind of mobilization that is needed. A study on ART patients in the Cote d'Ivoire showed no increase in self-reported risk behavior among ART patients who were counseled to maintain safe behavior ((Katzenstein, Laga, and Moatti 2003, 17 Suppl 3:S1-S4)). However, we know from biological studies that patients who are effectively adhering

to antiretroviral medication are in any case less likely to transmit infection during unprotected sex. The challenge lies elsewhere.

Patients who, thanks to their precise adherence to their medication regime, are in good health can be an important channel for reaching out to the much larger population of people whose risk behavior places them in danger of infection. With proper training, motivation and monitoring, patients can work to assure that AIDS treatment does not engender complacency and disinhibition among non-patients, but instead encourages reductions in their risk behavior.

One way to use such patients would be to build on the adherence support organizations mentioned above. When multiple adherence support organizations exist in a community, they can be judged against one another not only by their success at maintaining adherence among their members, but also on their efforts to reach out to non-members with HIV prevention interventions. Organizations which do well only on adherence would not lose their funding; reducing their funding might disrupt the treatment of their members. But neither would such poor performers receive funding to enroll additional members. Organizations which excel at both adherence support and outreach prevention would, on the other hand, be rewarded with funding for additional members. In this way through a process of muted competition among treatment support organizations, treatment subsidies would also be leveraging prevention efforts in the places that need both.

#### c) Expand access to male circumcision

The evidence that male circumcision (MC) protects men from HIV infection has accumulated now from both observational and experimental studies. The first observational study was the cross-country regression by Bongaarts and co-authors in 1989 (Bongaarts et al. 1989, 3:373-377) and showed a remarkable association between MC prevalence and HIV prevalence. Skeptics expressed doubt regarding the causal link since MC prevalence was correlated with religious affiliation, which might be directly responsible for differences in HIV prevalence because of religious differences in sexual mores. For example, one crosssection study of HIV prevalence found that prevalence of MC was statistically insignificant, when percent-Muslim and seven other socio-economic variables were controlled for (Over 1998:39-52).<sup>39</sup> However, in the last few years, randomized controlled trials in Uganda (Gray et al. 2007, 369:657-666), South Africa (Auvert et al. 2005, 2:e298) and Kenya (Bailey et al. 2007, 369:643-656) have confirmed that the association between MC and HIV is indeed causal. For example, the ethical review process halted the Kenyan trial after observing that 22 of the 1391 circumcised men became HIV infected compared to 47 among the 1393 uncircumcised group. Since the risk of becoming infected during the trial period was 53 % smaller for the circumcised, the researchers concluded that MC is comparable to a 50 % effective vaccination. Circumcision seemed to be equally protective in Uganda (51 % reduction in risk) and perhaps more so in South Africa (60 % reduction in risk). Furthermore, none of the studies was able to find evidence that circumcised men might be "disinhibited", increasing their risky behavior and thereby offsetting some of the advantage of the circumcision.

As the encouraging results on MC have accumulated, researchers have increasingly turned from the question of efficacy to that of feasibility. Small scale non-random studies have generally supported the feasibility of scaling up MC access to the general population in Africa. Building on these research results, PEPFAR should now allocate a substantial portion of its discretionary resources to making clean and safe circumcision at least as easily accessible to men as antiretroviral therapy in all the PEPFAR countries.

#### d) Integrate family planning with AIDS treatment

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<sup>&</sup>lt;sup>39</sup> A more recent cross-section analysis found a statistically significant impact of male circumcision but did not control for socio-economic variables (Drain et al. 2006, 6:172).

<sup>&</sup>lt;sup>40</sup> However the confidence intervals overlap.

<sup>&</sup>lt;sup>41</sup> Whether this would be true in South Asia, where the foreskin is a distinction of Hindu men, is a separate and potentially more difficult question.

Another key strategy to prevent infections, which has not been sufficiently deployed, is family planning. While programs to prevent mother to child transmission (PMTCT) of HIV are having increased success, they are still difficult and complicated. Every child that is infected despite PMTCT efforts will be costly to treat for his or her entire life. Furthermore, such children stand a greater than average chance of becoming orphans, despite the efficacy and increased availability of AIDS treatment.

In view of the private and social cost incurred for each HIV infected child, AIDS treatment programs and family planning programs should join forces to assure than every HIV-positive woman has free and easy access to the birth control method of her choice, without fear of stigmatization. Unfortunately, due to the lack of integration of family planning and AIDS treatment, there appears to be substantial unmet need for contraception among HIV positive women. As early as 1993 a study found that 60 percent of HIV positive women would prefer not to have more children (Allen et al. 1993, 83:705-710). Medical intervention to prevent mother to child transmission of HIV once pregnancy has occurred has been found to be less or equally cost-effective than family planning in several studies (Reynolds et al. 2006, 33:350-356;Stover et al. 2003;Sweat et al. 2004, 18:1661-1671). In a letter to the editor, three of the authors of these studies point out that the existing low levels of contraception in sub-Saharan Africa have probably prevented 173,000 HIV infected births each recent year and that provision of family planning services to the those with unmet need can avert an additional 160,000 HIV positive births every year (Reynolds, Steiner, and Cates 2005, 81:184-185).

#### e) Re-orient HIV testing toward couples

As a supplement to provider-initiated testing, PEPFAR should evaluate the feasibility and effectiveness of wide-scale couple counseling in the home. While couple counseling has been found to be effective with discordant couples (where one is HIV infected) (Allen et al. 1992, 268:3338-3343;Allen et al. 1992, 304:1605-1609;Allen, Serufilira, Gruber, Kegeles, Van de, Carael, and Coates 1993, 83:705-710;Padian et al. 1993, 6:1043-1048;Roth et al. 2001, 12:181-188), it has an even more promising role for concordant-negative couples, in which neither person is yet infected. Furthermore, a few studies suggest that people are more likely to accept couple counseling in their home than at health care facilities (Farquhar et al. 2004, 37:1620-1626;Matovu et al. 2002, 7:1064-1067;Were et al. 2003, 361:1569). When couples learn each others' HIV status as well as their own, and receive counseling about the dangers of unprotected sex outside the couple, such knowledge might not only increase condom use with other partners, but reduce the frequency of such partners. Thus, couple counseling, especially couple counseling in the couple's home, might be the intervention that would achieve Helen Epstein's elusive "invisible cure", by discouraging the practice of multiple concurrent partnerships thought to be a major contributor to the epidemic (Epstein 2007, 1st ed;Halperin and Epstein 2004, 364:4-6;Morris and Kretzschmar 1997, 11:641-648).

#### C. Ensure the AIDS Transition

Just as there have been demographic transitions and epidemiologic transitions which have occurred in the past, the world can aspire to accomplish an "AIDS Transition" in the next few decades.<sup>43</sup> What would an AIDS transition encompass?

First in the epidemiological dimension, an AIDS transition would see the growth of the number of people infected with HIV decrease below the growth of the number of people on treatment. Even with the enormous progress in the last few years, the number of people placed on treatment worldwide in 2007 was only about one-fourth the number of new HIV infections that year. So to accomplish the AIDS Transition, we will need to both accelerate treatment access AND greatly reduce the rate of new infections.

<sup>&</sup>lt;sup>42</sup> Her estimate rests on the assumption that the proportion of unwanted pregnancies is similar between HIV positive and HIV negative women. This assumption finds support in a recent working paper on Lesotho in which the author found no statistically significant difference in desire for children with respect to known HIV status (Adair 2007).

<sup>&</sup>lt;sup>43</sup> See (Over 2004:311-344) for discussion of the implications of an AIDS transition.

As outlined above, for the PEPFAR program the AIDS Transition can mean the program's gradual transformation from a predominately bilateral program to a more multilateral one. If the prevention part of the AIDS Transition is to succeed in PEPFAR countries, the millions of people receiving AIDS treatment must be used as a force for the dramatic expansion and improved effectiveness of prevention programs.

More generally the AIDS Transition must mean a refocusing of the rhetoric, goal-setting and results orientation that is gaining force in AIDS treatment to target also AIDS prevention. The next US president should assure that the successor to WHO's unsuccessful "3 by 5" program to expand treatment to three million by 2005 and its current program "Towards Universal Access by 2010" will be a program aimed at *preventing 90 percent of current annual infections by 2012*. Such a program should use all the means at available, including schools, adherence support groups, local governments. Measures of success must use biological markers of risk behavior, like pregnancy, HIV infection or infection with another sexually transmitted infection, not just self-reports.

The most forward-looking part of the AIDS Transition will be to broaden US research funding on AIDS. Because NIH's mandate is to focus on biomedical research, the critical questions of how to scale-up treatment programs and how to improve the effectiveness and reach of prevention programs are underresearched (Institute of Medicine 2007;Klag 2007). The next US president should ask Congress to channel ten percent of all AIDS research funding to health services research on the effective delivery of HIV/AIDS prevention and treatment services in a manner that complements, rather than undermines, other locally needed health care services.

President Bush's "emergency" AIDS assistance program to fifteen of the countries affected by the epidemic is in the best, generous traditions of American foreign assistance. PEPFAR has already prolonged the lives of more than a million people, provided care and support for orphans and other vulnerable children, and prevented many cases of HIV infection. Although the evidence is not yet in on the program's effects on the health care systems of all recipients, some countries' systems seem to have benefited from positive spillover effects from PEPFAR. Together with the Millennium Challenge Account, PEPFAR is arguably the Bush administration's most notable foreign policy success.

However, the research and analysis presented in this chapter suggest that the potential for several serious failures lies hidden within this apparent success. If the U.S. is seen to renege on its implied commitment to existing AIDS patients or if it is thought to have allowed treatment quality to degrade over time, failed to prevent new cases of HIV infection from swelling the ranks of those needing treatment, harmed the health care of patients who do not have AIDS, or facilitated the emergence and spread of drug-resistant forms of HIV, President Bush's initial success will metamorphose before our eyes into a deadly and shameful example of overreaching American incompetence—to be blamed inevitably on the new president. We argue that the next president can build on PEPFAR in such a way as to prevent these worst-case scenarios. If, in the existing fifteen PEPFAR focus countries, the next government can effectively manage the current AIDS treatment entitlement, prevent the future need for treatment, and help ensure the AIDS transition to the point that the disease becomes a manageable chronic condition, then the next president will deserve a full measure of credit for the long-run benefits of PEPFAR, credit equal to or greater than that due to President Bush for launching the program. This chapter has suggested some of the specific ways that the new president can avoid the worst-case scenarios and assure this desirable outcome.

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#### Annex A. A model for projecting future AIDS treatment costs

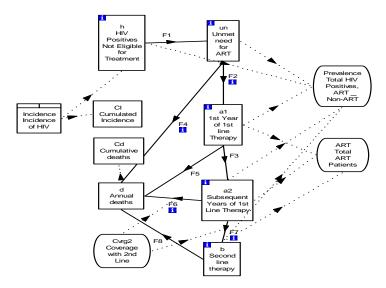


Figure 19. Flow diagram for predicting the future growth of AIDS treatment costs (Source: Author's construction using ModelMaker software.)<sup>44</sup>

Parameters of the projection model for predicting future AIDS treatment expenditures

Proportion of HIV+ newly eligible for ART	erate	.11
ART Death Rate during first year on 1st line	adrate1	.13
ART Death Rate during subsequent years on 1st line	adrate2	.04
ART Death Rate of AIDS patients on 2nd line	bdrate	.01
Non-ART Death Rate of AIDS patients	ndrate	.3
Starting coverage rate for 2nd line ART <sup>45</sup>	strtcov2	.05
Target coverage rate for 2nd line ART	trgtcov2	.95
2nd line ART to reach target in year	trgtyr	2016
Scale-up of 1st line modeled as constant proportion		
(1 - lambda) of unmet need, where lambda is constant		
across all countries and equal to:		
Historical scale up	lambda =	.82
Rapid scale up	lambda =	.05
Annual cost per patient of first-line drugs <sup>46</sup>		\$227
Annual cost per patient of second-line drugs		\$2,681
Annual cost per patient of clinic time		\$278

<sup>&</sup>lt;sup>44</sup> See (White 2007) for discussion of appropriate parameter values for the model and the Spectrum projection model for an alternative modeling platform: <a href="http://www.futuresinstitute.org/">http://www.futuresinstitute.org/</a>. On cost assumptions, see (Bollinger, Stover, and UNAIDS 2007).

<sup>&</sup>lt;sup>45</sup> The model embodies the assumption that, for those people who fail first-line ART, access to second-line ART expands along a logistic curve from about 5 percent of all patients needing it now to 95% of all patients needing it in 2016.

<sup>&</sup>lt;sup>46</sup> Drug costs are assumed to vary across countries with the 2006 GDP per capita of the country according to the patterns observed by WHO in that year and then to remain constant in any given country over time. While the costs of drugs may be reduced as markets for antiretroviral drugs become more contestable, the unit costs of achieving high ART uptake and strong adherence may increase at the same rate, leaving average costs per patient unchanged.

Annex B. Projected annual cost of treating AIDS patients in 15 focus countries by uptake and prevention scenarios (Thousands of 2006 US dollars)

Costs of AIDS treatment at historical uptake & 90% reduction in incidence each year				Costs of AIDS treatment at historical uptake & 5% reduction in incidence each year				
	1st line	2nd line	Total cost		1st line	2nd line	Total cost	
2006	529,785	191,727	721,512	2006	529,785	191,727	721,512	
2007	673,329	201,623	874,952	2007	673,329	201,623	874,952	
2008	874,949	227,439	1,102,388	2008	874,949	227,439	1,102,388	
2009	1,093,394	274,306	1,367,700	2009	1,093,394	274,306	1,367,700	
2010	1,303,451	353,146	1,656,597	2010	1,316,705	353,146	1,669,851	
2011	1,493,607	474,165	1,967,772	2011	1,537,707	474,165	2,011,872	
2012	1,659,169	645,144	2,304,313	2012	1,752,010	646,776	2,398,786	
2013	1,799,050	871,376	2,670,426	2013	1,956,904	879,399	2,836,303	
2014	1,914,054	1,155,985	3,070,039	2014	2,150,721	1,179,388	3,330,109	
2015	2,005,932	1,500,249	3,506,181	2015	2,332,462	1,553,030	3,885,492	
2016	2,076,820	1,903,999	3,980,819	2016	2,501,578	2,005,589	4,507,167	
2017	2,128,992	2,324,288	4,453,280	2017	2,657,823	2,493,208	5,151,031	
2018	2,164,638	2,756,281	4,920,919	2018	2,801,161	3,012,715	5,813,876	
2019	2,185,840	3,195,719	5,381,559	2019	2,931,717	3,560,905	6,492,622	
2020	2,194,497	3,638,869	5,833,366	2020	3,049,732	4,134,636	7,184,368	
Total	24,097,507	19,714,316	Least costly 43,811,823	Total	28,159,977	21,188,052	49,348,029	
By presid	dential term							
<b>'09-'12</b>	5,549,621	1,746,761	7,296,382		5,699,816	1,748,393	7,448,209	
<b>'13-'16</b>	7,795,856	5,431,609	13,227,465		8,941,665	5,617,406	14,559,071	
	Costs of AIDS treatment at rapid uptake & 90% reduction in incidence each year				Costs of AIDS treatment at rapid uptake & 5% reduction in incidence each year			
	1st line	2nd line	Total cost		1st line	2nd line	Total cost	
2006	529,785	191,727	721,512	2006	529,785	191,727	721,512	
2007	1,635,364	201,623	1,836,987	2007	1,635,364	201,623	1,836,987	
2008	2,307,005	227,439	2,534,444	2008	2,307,005	227,439	2,534,444	
2009	2,970,273	335,242	3,305,515	2009	2,970,273	335,242	3,305,515	
2010	3,528,288	537,685	4,065,973	2010	3,604,610	537,685	4,142,295	
2011	3,989,774	857,925	4,847,699	2011	4,206,920	857,925	5,064,845	
2012 2013	4,366,528	1,308,550	5,675,078	2012	4,775,381	1,317,404	6,092,785	
	4,669,214	1,896,367	6,565,581	2013	5,308,801	1,935,101	7,243,902	
2014	4,907,290	2,624,207	7,531,497	2014	5,806,506	2,727,520	8,534,026	
2015 2016	5,089,106 5,222,058	3,491,710 4,496,040	8,580,816 9,718,098	2015 2016	6,268,233 6,694,088	3,708,719 4,890,296	9,976,952 11,584,384	
2017	5,312,678	5,530,143	10,842,821	2017	7,084,481	6,156,945		
			11,949,917			7,500,065	13,241,426	
2018 2019	5,366,727 5,389,291	6,583,190 7,645,843	13,035,134	2018 2019	7,440,050 7,761,645	8,911,297	14,940,115 16,672,942	
2019	5,384,857	8,710,115	14,094,972	2019	8,050,268	10,382,518	18,432,786	
2020	3,304,037	0,710,113	14,094,972	2020	0,030,200	10,302,310	Most costly	
Total	60,668,238	44,637,806	105,306,044	Total	74,443,410	49,881,506	124,324,916	
By presid	dential term							
'09-'12	14,854,863	3,039,402	17,894,265		15,557,184	3,048,256	18,605,440	
<b>'13-'16</b>	19,887,668	12,508,324	32,395,992		24,077,628	13,261,636	37,339,264	
Source: Author's calculations based on assumptions in Annex A.								