The Prize Fund for HIV/AIDS

A New Paradigm for Supporting Sustainable Innovation and Access to New Drugs for AIDS: De-Linking Markets for Products from Markets for Innovation

May 26, 2011

Introduction

The Prize Fund for HIV/AIDS (S. 1138, 112th Congress) is a proposal to change the system of rewards to induce R&D investments.

One fundamental element is to separate the markets for products from the markets for innovation. The proposed legislation would eliminate patent and other intellectual property barriers to the introduction of generic medicines for AIDS. Replacing product monopolies would be a new Prize Fund for HIV/AIDS that would provide more than $3 billion in annual rewards for useful investments in R&D for new treatments for HIV/AIDS.

Patents would still be available for HIV/AIDS inventions, and valuable in making claims against the Prize Fund, but they would not be used to block generic competition. Open source research methods would also be eligible to receive rewards from the Prize Fund.

By **de-linking** R&D incentives from product prices, it is possible to price drugs at marginal costs, eliminating waiting lists for access to AIDS drugs, and eliminating price sensitive drug formularies. De-linkage also makes it possible to reward a wider range of activities. The Prize Fund for the HIV/AIDS reward system includes an **open source dividend** and system of **competitive intermediaries** to reward interim and translational development activities.

The global dimension is addressed by the creation of a Donor Prize Fund, which is funded out of contributions for humanitarian programs to treat AIDS. The money from the Donor Prize Fund is only available to reward products that are openly licensed to permit competition from generic suppliers.

The reforms in the Prize Fund for HIV/AIDS are designed to lower the overall costs of treatments for HIV/AIDS, while increasing access and innovation.

Background

Numbers of persons needing antiretroviral drugs

According to the Centers for Disease Control and Prevention, there are more than one million persons living with HIV in the United States. CDC estimates more than 56 thousand persons are newly infected with HIV every year, and 18 thousand persons with AIDS die every year.

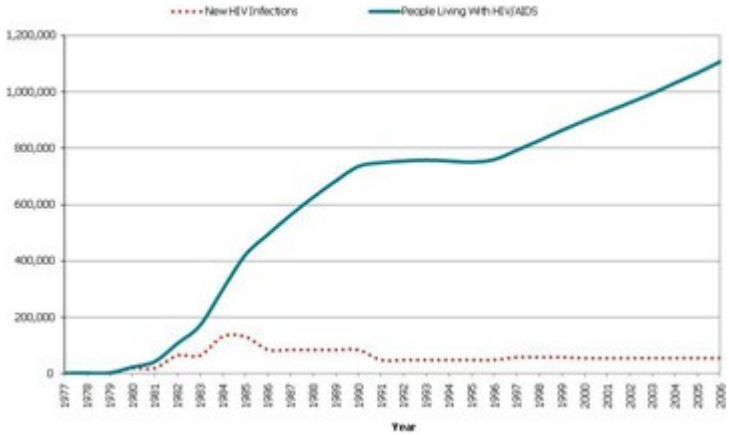

Figure 1: Hall HI, Song R, Rhodes P. et al. Estimation of HIV Incidence in the US. JAMA 2008;300: 520-529. CDC. HIV prevalence estimates--US 2006.

A study recently published in the journal *Clinical Infectious Diseases* that focuses on the United States, estimates that 21 percent of persons who are HIV+ are undiagnosed, and among the 79 percent who have been diagnosed as HIV+, just 30 percent are receiving antiretroviral drugs.

Table 1: Diagnosis, care and access to ARV drugs in the United States

Status	**Number of persons**	**Percent HIV+**	**Percent Diagnosed HIV+**
HIV Positive	1,106,400	100%	
HIV-Diagnosed	874,056	79%	100%
Linked to HIV care	655,542	59%	75%
Retained in HIV care	437,028	40%	50%
Need Antiretroviral Therapy	349,622	32%	40%
Receiving Antiretroviral Therapy	262,217	24%	30%
Adherent/Undetectable	209,773	19%	24%

Source: Gardiner, McLees, Steiner, del Rio and Burman, "The Spectrum of Engagement in HIV Care and its Relevance to Test-and-Treat Strategies for Prevention of HIV Infection," Clinical Infectious Diseases, 2011:52 (15 March), 793-800.

According to the World Health Organization, there are more than 33 million persons living with HIV worldwide. Globally, the rate of new infections is estimated to be around 7 thousand persons per day, or 2.5 million per year. More than 90 percent of persons who are HIV+ live in developing countries.

The number of persons receiving antiretroviral drugs in lower and middle income countries is estimated to be roughly six million.

UNAIDS predicts that more than 20 million persons in developing countries will need antiretroviral drugs by 2025.

All of these people will die without access to life saving medicines.

A new NIH funded study suggests the standard for care regarding access to antiretroviral drugs may change significantly, as research has established that the lack of access to ARV treatments not only harms persons who are HIV+, but also contributes to a higher rate of infections. A May 12, 2011 press release by the NIH reports that "earlier initiation of antiretrovirals led to a 96 percent reduction in HIV transmission to the HIV-uninfected partner."[1]

The Need for Innovation

Every patient receiving HIV drugs struggles with their side effects, and a life long battle with drug resistance.

Since 1996, the rate of innovation for new AIDS drugs has been steady, but fairly slow. For most patients, the newer drugs do a better job of fighting AIDS with fewer side effects, and easier methods of delivery.

AIDS treatment advocates want to expand and accelerate innovation for new HIV/AIDS treatments. This requires (1) sufficient spending by governments on grants for AIDS research, (2) sustainable sources of revenue to reward successful private investments in medically important innovations in treatments for AIDS, and (3) new incentives to motivate more openness and sharing of knowledge, data, materials and technology.

Costs of Antiretroviral Drugs

Governments need to address the soaring costs of AIDS treatment. The United States is now spending on average more than $9 thousand annually on antiretroviral (ARV) drugs for each of the 1 million persons living with HIV in the United States, a number that would be far higher if a larger percentage of persons living with HIV were receiving treatment or taking newer drugs.

According to IMS, from 2006 to 2010, the cost of ARV drugs in the U.S. Market increased from $5.6 to $9.2 billion. The annual rate of change in ARV sales was 13.2 percent.[2]

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1 See: NIH press release: "Treating HIV-infected people with antiretrovirals significantly reduces transmission to partners," May 12, 2011; and Donald G. McNeil, Jr., "Early H.I.V. Therapy Sharply Curbs Transmission," *New York Times,* May 12, 2011.

2 For the market for all prescription drugs, the average rate of change was 3.3 percent.

Table 2: Sales of ARV drugs in United States

Year	Sales of ARV Drugs in billions of US dollars	Rate of Change from Previous Year
2006	$5.6	
2007	$6.2	10.7%
2008	$7.1	14.5%
2009	$8.2	15.5%
2010	$9.2	12.2%
	Average:	13.2%

Source: IMS Health, National Sales Perspectives, Dec 2010

The largest selling ARV regime in the United States is the three drug combination product Atripla. The average retail price of Atripla is more than $24 thousand per year. Some newer four drug protease inhibitor regimes are priced at more than $35 thousand per year.

Globally, the United States is the largest purchaser of ARV drugs in the developing world. Most of the persons living in developing countries are now being treated with a three drug combination of 3TC+d4T+NVP, a combination no longer considered appropriate as a first line treatment regime in the United States, when compared to better alternatives. The annual cost of this combination was $350 in January of 2001, $250 later that year, and is available for less than $100 today.

As patients predictably develop resistance to this older combination, they will need to migrate to newer and far more expensive HIV drugs. The existence of donor supported programs to pay for HIV drugs has encouraged more aggressive patenting of HIV drugs in developing countries, including in Sub-Saharan Africa. Some important newer AIDS drugs are priced at anywhere from $1,000 to $12,000 per year in developing countries.

The high cost of AIDS drug has a negative impact on access everywhere.

The U.S. federal and state subsidized AIDS Drug Assistance Programs (ADAP) are facing a funding crisis. By May 19, 2011, ten U.S. States and Puerto Rico were reporting waiting lists of 8,310 patients for enrollment in their ADAP programs. Eighteen states had implemented cost containment measures such as reduced formularies, capped enrollment, lower eligible incomes or high co-payments from patients. Thirteen states were considering additional cost control measures.[3]

[3] ADAP Watch, National Alliance of State & Territorial AIDS Directors, April 29, 2011. Note that some states are counted in more than one category. For example, Florida reported a waiting list of 3,752 patients, a reduced formulary, the transition of 5,403 clients to Welvisa, and is considering lower financial eligibility.

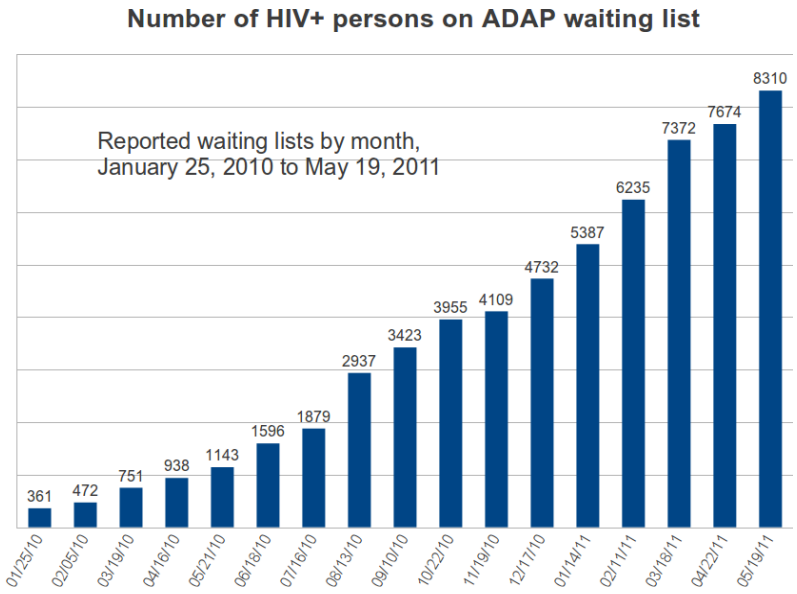

Figure 2: Since January 2009, ADAP waiting lists have seen large increases

Many persons living with HIV who do not qualify for ADAP programs also face growing hardships in obtaining access to antiretroviral drugs, including restrictive formularies, expensive co-payments and expensive insurance premiums.

In developing countries, the combination of the higher cost for new drugs and lower enthusiasm for funding AIDS programs during the financial crisis is contributing to fatal limits on enrollment in AIDS programs, and to use of inferior drugs.

The challenges of dealing with drug resistance, new infections, high prices and aggressive price increases, have collectively contributed to a major crisis in terms of access and the sustainability of access to new medicines for HIV/AIDS. This crisis affects more than a million persons in the United States and tens of millions of persons worldwide.

It is necessary to explore new ways of effectively dealing with the high cost of new drugs, while ensuring robust innovation for new treatments.

The Prize Fund for HIV/AIDS

The bill creating the Prize Fund for HIV/AIDS seeks to reconcile the dual objectives of supporting innovation and access to new AIDS treatments. It does so by radically changing the mechanisms to reward investments in R&D.

First, the legislation eliminates all legal monopolies on the sale of qualifying products for the treatment of HIV/AIDS, making it possible to buy inexpensive generic versions from competitive suppliers. Competition is expected to lower the cost of drugs by more than $7 billion per year for the U.S. domestic market, with the saving shared by health insurers and patients.

The rewards for innovation would be provide by the new Prize Fund for HIV/AIDS that would be funded at 0.0002 of the gross domestic product of the United States, an amount equal to more than $3 billion per year at current levels of GDP.

The Prize Fund for HIV/AIDS would be co-funded by the federal government and private health insurance and reimbursement programs. Overall, the costs of the prize fund would be less than the cost now associated with the purchase of expensive medicines.

The $3 billion per year in innovation prizes would be allocated through three different programs:

End product prizes.

Some of the prize money would be allocated to the first person that registers a "Qualifying Treatment for HIV/AIDS," or a new manufacturing process for such product.

The persons entitled to these prizes would be, for a drug or biological product, the first person to receive FDA marketing approval, and for a manufacturing process, the holder of the patent with respect to such process. Suppliers of new innovations would compete against each other for shares of the prize fund money. In considering the claims, the Prize Fund Director would consider, among other factors:

(a) The number of patients who benefit from the drug, biological product, or manufacturing process involved,
(b) The needs of special populations, such as pediatric AIDS patients,
(c) The incremental therapeutic benefit of the drug, biological product, or manufacturing process involved as compared to existing drugs, biological products, and manufacturing processes available to treat the same disease or condition, and
(d) The improved efficiency of manufacturing processes.

Products or processes would eligible to participate in the prize fund for 10 years. Each annual competition for prize fund rewards would be based upon the best evidence available in that year.

For cases where drugs, biological products, or manufacturing processes are developed at roughly the same time, the comparison is to products that were not recently developed.

Open Source Dividend

In order to induce greater access and the open sharing of knowledge, data, materials and technology, at least five percent of the prize payments will be dedicated to Open Source Dividend Prizes. At current levels of GDP, this would be at least $150 million per year.

The open source dividend prizes would be allocated to reward the open, non-discriminatory and royalty free sharing of knowledge, data, materials and technology that has contributed to the development of the new medicines or manufacturing efficiencies that qualified for the end product prizes.

In this part of the competition, the Prize Fund would consider "the extent to which knowledge, data, materials and technology that are openly shared have contributed to the successful development of new products or improved processes for manufacturing products."

Competitive Intermediaries for interim development

The Prize Fund Director would have the authority to authorize multiple non-profit intermediaries to manage prize fund payments to reward projects for interim development development of new treatments for HIV/AIDS, or for open source dividend prizes. Such intermediaries would compete for funding from non-federal entities that co-fund the Prize Fund for HIV/AIDS.

These competitive entities would provide prizes to persons or communities that achieved useful R&D outcomes of an interim nature. Since it is more controversial to value such achievements, the strategy is to create a competitive process that legitimizes the choices of the entities that make the decisions about the prizes.

The interim prizes require open, non-discriminatory and royalty free licenses to relevant intellectual property rights.

The Donor Prize Fund

Most persons with HIV/AIDS live in developing countries, where the United States is the largest purchaser of antiretroviral drugs. In order to further de-link product prices from research and development incentives, and to facilitate the supply of low cost generic drugs for the treatment of HIV/AIDS in developing countries, the Secretary of DHHS is required to establish a Donor Innovation Prize Fund.

The Donor Prize Fund will receive an amount equal to 10 percent of the cost of AIDS drugs in programs supported by PEPFAR or other federally funded programs to support the treatment of HIV/AIDS in developing countries.

The funds from the Donor Innovation Prize Fund are only available to reward products that permit open competition for products in developing countries, either by not patenting products, providing non-discriminatory royalty free open licenses to all patents and other intellectual property claims on at least a field of use for the treatment of HIV/AIDS in developing countries, or through licenses to the Medicine Patent Pool.