until it's over AIDS ACTION

POLICY BRIEF

july 2005

The AIDS Drug Assistance Program

Following the Epidemic: Past, Present, and Future

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Introduction

The AIDS Drug Assistance Program (ADAP) is a federally funded provider of medication for the treatment of HIV infection. Without this program, thousands of individuals who are uninsured or underinsured would not receive the medications that keep them alive, healthy and productive. The Program has been re-crafted several times over the last two decades to meet the growing complexity and cost of treating HIV infection. This policy brief provides an overview of the evolution and current reality of the AIDS Drug Assistance Program as it "follows" the epidemic—as part of a federal response to the need for HIV medical care and treatment. The policy brief connects the history of HIV with federal legislation, discusses ADAP funding over time, explains the Program's current structural realities, and

ends with an assessment of the role of the AIDS Drug Assistance Program in effecting positive change in the U.S. epidemic.

History of HIV and Federal Legislation

The first years of the HIV epidemic in the United States were marked by explosive rates of illness and morbidity. First reported in 1980, this yet unnamed illness was seen to cause a critical

weakening of the immune system. People lost their ability to fight infection in the body, and with their immune systems suppressed, grave diseases or cancers proliferated and ultimately ended lives. It was not until 1984 that the definitive cause for this Acquired Immune Deficiency Syndrome, more commonly known as AIDS, was identified as a transmittable virus: the Human Immunodeficiency Virus or HIV. Soon it was understood that, if left untreated, the human body could endure only ten years of this infection before it weakened and died. As a new public health crisis, the HIV epidemic warranted a strong and immediate response from the medical science community and pharmacology. But HIV medical research and drug development did not move as quickly as the disease itself, and it wasn't until the late 1980s that treatments began to emerge.

In 1987 the Food and Drug Administration approved the first medication for the treatment of HIV. Known both as zidovudine and AZT, the drug was not made readily available to all people diagnosed with HIV infection. Furthermore, the treatment did not guarantee substantial health improvements, and it was expensive. A year of AZT treatment cost approximately \$10,000.

This new virus, HIV, was showing itself to be a costly and difficult infection to treat, and even when only one pharmaceutical drug was available, it was beyond the economic reach of many. With mounting pressure from a newly formed HIV advocacy community, Congress approved a new initiative in 1987, the AZT Assistance Program, and allocated \$30 million to state health departments for purchase and dissemination of AZT to those who could not afford it.

Three years later, in 1990, Congress passed and funded the Ryan White Comprehensive AIDS Resources Emergency (CARE) Act. This bipartisan legislation was designed to provide health care to HIV-positive Americans who were either uninsured or underinsured. As part of the country's broader system of health care financing, this new federal program was intended to work

in tandem with Medicaid, Medicare and private insurance.

The CARE Act was crafted with four principal components referred to as Titles (Title I,II,III and IV) that were designed to address specific jurisdictions and populations heavily impacted by HIV. The Titles of the CARE Act are characterized by their different funding capacities: grants to cities and states; direct grants to health care providers; targeted funds for HIV prescription medications, dental

services, and professional training; and funds for vulnerable communities. The CARE Act offered a comprehensive programmatic response to the epidemic, and is, to this day, the federal government's chief funding source dedicated exclusively to HIV.

The CARE Act, a discretionary program (versus entitlement programs such as Medicaid or Medicare), was set to be reauthorized by Congress every five years. During the initial authorization process in 1990, the AZT Assistance Program was renamed the AIDS Drug Assistance Program (ADAP) and was written into Title II, the component of the CARE Act specifically focused on providing resources to state jurisdictions for HIV treatment and care.

Between 1990 and the first reauthorization process in 1996, monies used for ADAP were drawn from Title II funding allocations—generally administered by state health departments.* The amount of money dedicated to ADAP was decided by each state separately. This funding structure was changed in the first reauthorization of the CARE Act in 1996,



when ADAP was granted its own federal earmark. (An earmark is an allocation within a funding stream that can only be used for a specific program.) In 1996 the ADAP earmark was set at \$52 million.\(^1\) Even though ADAP was given its own funding allocation, it still remains within Title II of the CARE Act.

Treatment Advancement

That same year, in 1996, more effective medications became available to treat HIV infection. Prescribed in combination with each other, the drugs were referred to as Highly Active Anti-Retroviral Treatment (HAART). The standard of care had become more than just AZT – it included a combination of drug therapies that worked together to strengthen each other's effectiveness, making them "highly active." Science had shown that to inhibit replication of the virus in the body, combinations of two, three, four and five drugs taken every day were more effective than a single agent working alone. Newly trained HIV specialists were now prescribing this treatment to patients while in good health, before the immune system weakened, long before the person could develop an AIDS diagnosis. These combined drug regimens dramatically

increased the life span of people living with HIV, increased the length of time a person would need treatment, and increased the cost of treatment as well.

HIV had matured into a resource-intensive infection. A person diagnosed with HIV must visit a trained HIV specialist every three to six months. Blood samples are frequently drawn for multiple laboratory

tests, and only then can decisions be made about the initiation or modification of an anti-retroviral regimen. This process for one single person living with HIV continues for life, involving numerous medical professionals and thousands of doses of medications. What's more, interrupting or stopping one's treatment altogether can stimulate the virus to reproduce, causing damage to a person's health that is difficult or impossible to restore.

To meet the growing complexity and cost of advances in treatment and multiple drug regimens, the federal program designed to provide HIV medications has been configured three times: in 1987 the AZT Assistance Program was created; in 1990 the program transitioned to ADAP within Title II of the CARE Act; and in 1996 a federal earmark of specific ADAP funding was allocated.

Current Structural Realities

The evolution of HIV infection over the last 25 years (1980 – 2005), from a terminal condition to a disease requiring continuous medical management, has immediate implications for the AIDS Drug Assistance Program. Overall, the federally funded ADAP - comprised of individually managed Programs in all 50 states and seven territories - is faced with growing numbers of eligible participants along with the substantial costs

of HIV treatment regimens. As a result, many states have experienced "budget shortfalls," meaning the demand for services frequently exceeds the available resources. If a budget shortfall occurs, the state can either allocate other funds to its ADAP, or implement restrictions on the Program such as limiting or closing enrollment. And because all states and territories administer their Programs independently, marked differences in the availability and quality of services provided by the 57 ADAPs now exist.

Program Benefits

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ADAP funding provides assistance for the purchase of treatments and devices that are essential to administer treatments, facilitates access to treatments, and supports adherence to treatment regimens and related medical monitoring. ² As of June 2004, ADAP was serving 136,000 individuals in all 57 states and territories, or almost one-third of all HIV-positive people in the country who are receiving care. Of these individuals, 94,577 were receiving medications through the Program, and thousands more were receiving subsidies for part or all of their insurance coverage³.

Income Eligibility

The eligibility criteria for a person to participate in ADAP differ from state to state. For example, most states have an eligibility criterion that corresponds to measures of poverty (the Federal Poverty Level in 2005 is \$9,570 for a single person).⁴ Income eligibility limits can range from 125% to 500% above the Federal Poverty Level. Although

information varies on the average cost of treatment, antiretroviral regimens currently cost between \$12,000 and \$28,000 a year, depending on the specific combination an individual is prescribed.⁵ Even people who have incomes two or three times the Federal Poverty Level will require assistance with these treatments if they are to continue in good health while living with HIV.

Drug Formularies

Drug formularies, or the list of medications that state ADAPs will cover for a patient, present significant disparities. Some ADAPs will cover only certain drugs within the three main classes of anti-retrovirals.** For example, one state covers no Protease Inhibitors, and another covers only two of the three approved Non Nucleoside Reverse Transcriptase Inhibitors.⁶

The newest class of anti-retroviral drug options is Entry Inhibitors, and there is currently only one approved drug in this class: Fuzeon. This drug, which is administered subcutaneously, is priced at over \$20,000 a year, and is prescribed when all other anti-retroviral therapies have been exhausted. For many HIV-positive people, it is a last resort. Ten state ADAPs do not cover Fuzeon. ⁷

Also critical to the management of HIV infection in the human body are drugs prescribed for the prevention and treatment of

ADAP Timeline

Policy · Surveillance · Treatment · Resources

2010	Fourth reauthorization scheduled	? living AIDS cases	? estimated living with HIV	? available ARVs	Annual cost of ARV treatment \$? - \$?	Total ADAP budget will be \$?	ADAP will serve ? people	? million people will be uninsured	
2005	Third reauthorization Fou scheduled	405,926 living AIDS cases ¹ ?	1,100,000 estimated living ? e	25 available ARVs²	Annual cost of ARV A treatment \$12,000 - t	Total ADAP budget is \$1.2 billion ⁸	ADAP serves 136,000 Apeople	45 million people uninsured ⁵	
2000	Second CARE Act reauthorization	312,946 living AIDS cases ¹ 40	800,000 to 900,000 estimated living with HIV ⁹	17 available ARVs²	Annual cost of ARV treatment \$9,000 - \$20,000	Total ADAP budget is \$779 million ⁸	ADAP serves 125,800 people [®]	39.8 million people uninsured ⁵	
1996	First CARE Act reauthorization	223,000 living AIDS cases ¹	650,000 to 900,000 estimated living with HIV $^{ m e}$	9 available ARVs²	Annual cost of ARV treatment \$12,000 - \$18,000 ⁷	Total ADAP budget is \$200.4 million ⁸	ADAP serves 63,000 people ⁸	41.7 million people uninsured ⁵	
1990	CARE Act authorized	161,070 cumulative AIDS cases ¹	(Disputed number) estimated living with HIV	1 available ARV^2	Annual cost of ARV treatment \$10,000 ³	Total ADAP budget is \$(<u>unreported)</u>	ADAP serves (<u>unreported</u> <u>number</u>) people	34.7 million people uninsured ⁵	
1987	Pre-CARE Act legislation	49,743 cumulative AIDS cases	(Disputed number) estimated living with HIV	1 available anti-retroviral treatment (ARV) - AZT ²	Annual cost of ARV treatment \$10,000 ³	AZT Assistance Program budget is \$30 million ⁴	AZT Assistance Program serves (<u>unreported</u> <u>number</u>) people	31 million people uninsured ⁵	



opportunistic infections. These medications are used to mitigate diseases and infections that develop due to a compromised immune system. As of September 2004, the FDA had identified 16 such drugs. Only in four states does ADAP cover all 16, and one state does not cover any medications to prevent or treat opportunistic infections.⁸

Waiting Lists

In addition to restricting eligibility and limiting drug formularies, which are often referred to as "cost containment measures," many states implemented waiting lists beginning in 2003 to offset budget shortfalls. In these cases, individuals eligible for ADAP services are placed on a waiting list, and are unable to receive medications until their state ADAP receives the necessary funds. The time a person spends on a waiting list can vary substantially among states. Moving from the waiting list into the Program is sometimes contingent on another person being removed from the existing participant roster, or on the state's decision to prioritize one set of clinical conditions over another. In May 2005, the National Alliance of State and Territorial AIDS Directors (NASTAD) announced that ten states had active waiting lists, ranging from 14 to 723 people—a total of 1,891 individuals.9 Furthermore, some states do not obtain or house this information, and some individuals need access to ADAP's services but are discouraged from completing the application forms upon learning that enrollment is closed. These situations create unofficial or "invisible" waiting lists of people. The scope of this population is impossible to monitor.

In June of 2004, President Bush announced a \$20 million dollar emergency funding priority to eliminate ADAP waiting lists. NASTAD reported that the President's Initiative provided medications to 1,438 people or about 75% of those on all official waiting lists. However, despite the \$20 million Initiative, 453 (25% of the total) individuals were not removed from waiting lists. The Initiative expires in September 2005, and at this writing, there is no plan in place to ensure that the people who began treatment through this initiative can continue to receive their mediations.

Participant Relocation

Citizens in the United States frequently relocate within the country. People move for a variety of reasons, including changes in work, familial, health, and personal circumstances. According to a report by the U.S. Census Bureau, 22 million Americans moved states at least once between the years 1995 and 2000.

While HIV- positive individuals consider relocation at the same frequency and for the same reasons as the general population, their ability to do so may be impeded by differences in state managed health insurance programs, such as ADAP. The inconsistency of program access among ADAPs makes it difficult or impossible for HIV-positive individuals to relocate their lives, jobs, and families to different states and maintain a continuous level of necessary medical care and treatment.

Funding

Within Title II of the CARE Act, there are two primary funding streams: a Title II "base" allocation and an ADAP earmark. (Base allocation + ADAP earmark = Total Title II allocation.) Funding for a state's Title II base allocation and ADAP earmark is determined by its proportion or "share" of the total U.S. estimated living AIDS cases. The ADAP earmark is intended primarily to cover the costs of HIV medications for uninsured and underinsured HIV- positive individuals.

There are significant differences in how each state funds its ADAP. States supplement their ADAP budget with a "match," a financial contribution from the state proportionally based on the federal allocation of dollars. In some states, the Program is not supplemented at all by state revenue; in others, there is a considerable commitment. For example, one state draws 58% of its total ADAP budget from state revenue.¹²

In 2000, during the second reauthorization of the CARE Act, Title II Supplemental Grants were created. This provision was created for states with existing structural difficulties such as severe budget shortfalls. Congress is required to allocate 3% of the ADAP earmark to Supplemental Grants. In order to be eligible for these grants, states must demonstrate that they are experiencing financial limitations within their Program, and must contribute one state revenue dollar for every four federal dollars received. In 2004, 18 states received supplemental grants.

From 1996 to 2005, each of the four Titles' budgets has grown in response to the costly demands of the epidemic; however, some funding allocations have grown at much greater rates than others. For example, the ADAP earmark has grown 1,514% since 1996, while the Title II base has only grown 166%. The following table demonstrates the significantly larger growth of the ADAP funding as compared to all other Ryan White CARE Act Title allocations.¹³

Table 1:

CARE Act Titles	1996	2005	% growth						
Title I allocations	\$391,700,000	\$617,720,000	157%						
Title II base	\$208,847,000	\$348,338,000	166%						
Title II ADAP									
earmark	\$52,000,000	\$787,521,000	1,514%						
Title III allocations	\$56,918,000	\$198,023,000	347%						
Title IV allocations	\$29,000,000	\$73,425,000	253%						

The percentage growth depicted in Table 1 reflects the federal effort to respond to the constantly changing epidemic. However, the significant increase in the ADAP earmark does not meet the economic requirements for treating a growing population of people infected with HIV.

In addition to the federal earmark, state revenues and supplemental grants, other funds are used to cover shortfalls in a state's ADAP budget. Monies re-directed from Title I and Title II base allocations, as well as unexpended or "carryover" dollars



from other CARE Act programs are frequently utilized. These different funding mechanisms comprise the final or "total" ADAP budget. This amount is shown in the ADAP Timeline included in this policy brief.

Health Outcome Data

Recently, concerns have been raised by advocates, members of Congress and health care financing analysts that the CARE Act has not consistently measured the health outcomes of people using different CARE Act-funded services.¹⁴ Outcome measurements serve two fundamental purposes—to monitor the effectiveness of care and treatment provided by specific services, and to evaluate the benefits and results of an investment of federal dollars.

The AIDS Drug Assistance Program has a unique opportunity to demonstrate a clear correlation between HIV treatment and health outcomes. Unlike social service programs that often experience difficulty measuring changes in participants' health, ADAP is a primary care intervention and can be definitively linked to health outcomes by measuring the clinical indicators of HIV infection.***

Any available health measures received by ADAP are normally reported to the state agency that is managing the Program, which is often the state Department of Health. State health departments have full discretion for reporting or not reporting their program's outcomes; therefore, information on health outcomes for the aggregate of enrollees is not accessible and thusly not evaluated. Moreover, these data are not available to the public or to Congress.

The Future

The Centers for Disease Control and Prevention announced in June 2005 that more than one million Americans are living with HIV.15 Half of this population is currently receiving medical treatment. Among the other half million HIV-positive Americans, 250,000 are not aware of their infection and consequently are not receiving regular medical care for HIV. The other 250,000, though aware of their infection, are also not receiving regular medical care.¹⁶ This means that the 500,000 HIV-positive people in the U.S. who are not currently receiving medical care, will, at some time in the future, require care and treatment.

Recent studies have also documented the relationship between a person receiving medical care for HIV infection and the transmission of the virus to another person. These studies show that a person who has received a diagnosis for HIV and is receiving care is more likely to make decisions that prevent the transmission of the virus.¹⁷ An HIV-positive person not receiving care can make uninformed decisions which could result in viral transmission and, consequently, in new infections.

These studies clearly indicate that strategic planning is needed to counter the growth and complexity of the domestic HIV epidemic. Yet if the ADAP structure is overburdened and cannot offer sufficient care and treatment to HIV-positive people, there will be serious and measurable consequences. First and foremost, populations of people will suffer declining health and premature death. While this occurs, another real but hidden consequence will also be in progress: the constant production of new HIV infections transmitted by people who cannot successfully access the care they need. Current data clearly indicate that an insufficient and shortsighted AIDS Drug Assistance Program will not only produce premature mortalities, but will also contribute to an untold number of new HIV infections in this country.

Conclusion

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The HIV epidemic of 2005 is greatly different than the epidemic of 1990 when the CARE Act was first created. Today a person taking combined treatment regimens for HIV is committed to taking the medications for life. In this decade, the life expectancy for a person infected with HIV far exceeds the ten

year mark of the 1980s—if the person has access to continuous medical care and treatment

The third reauthorization of the Ryan White CARE Act is an historical opportunity to examine the federal government's success in altering the course of the HIV epidemic in this country. Even though all parts of the legislation are considered and analyzed, it is the AIDS Drug Assistance Program that receives the greatest amount of funding of all the

CARE Act components, and should therefore be subject to the highest grade of scrutiny from both legislators and citizens alike.

The opportunity to question and strengthen the federal government's role continues beyond any targeted month or year on the legislative calendar. Nevertheless, it is indisputable that the 2005 reauthorization process is a unique occasion. It is a time for our federal legislators to make decisions that will be. for better or for worse, lasting in their consequence.

Both legislators and advocates need to recognize the changed landscape of HIV and move ahead to assume strategic leadership. To that end, the AIDS Drug Assistance Program could very well move beyond its role of merely responding to the repercussions of HIV or "following the epidemic." Instead, policy makers can make committed programmatic decisions for ADAP that will steer our country in a new direction—toward greater health and productivity for people living with the virus, toward fewer new infections, and before long, toward the epidemic's final resolution in the United States.



Endnotes — Policy Brief

- Department of Health and Human Services (HHS). "Ryan White CARE Act: Appropriations History". Available online at http://hab.hrsa.gov/history.htm
- ² Ryan White CARE Act: Amendments of 2000, Public Law 106-345, 114 stat 1319, SEC. 2616 (c).
- ³ Kaiser Family Foundation (KFF). "HIV/AIDS Policy Fact Sheet: AIDS Drug Assistance Programs." April 2005.
- ⁴ 70 Fed. Reg. pp. 8373-8375 (February 18, 2005).
- ⁵ This estimate was derived through consultation with leading HIV treatment experts. Authors took 80% of the Average Wholesale Price (AWP) of commonly prescribed drug therapies (e.g., Combivir + Sustiva or Combivir + Fuzeon + Aptivus/Norvir-not on market yet). 80% of the AWP is approximately what third party payers such as insurance programs and ADAP will pay for prescription drugs.
- ⁶ Kaiser Family Foundation. ADAP Monitoring Project, April 2005
 ⁷ Ibid
- 8 Ibid
- ⁹ National Association of State and Territorial AIDS Directors (NASTAD). "The ADAP Watch." June 8, 2005
- 10 Ibid
- U.S. Bureau of the Census. 2003. Domestic Migration Across Regions, Divisions, and States: 1995 to 2000. Washington, DC.
- ¹² Kaiser Family Foundation. ADAP Monitoring Project, April 2005
- Department of Health and Human Services (HHS). "Ryan White CARE Act: Appropriations History". Available online at http://hab.hrsa.gov/history.htm
- ¹⁴ Institute of Medicine. "Measuring What Matters: Allocation, Planning, and Quality Assessment for the Ryan White CARE Act." November, 2003. pp. 2-3. (In the second reauthorization of the CARE Act in 2000, Congress commissioned the Institute of Medicine (IOM) to examine "The availability of health outcome measures for HIV primary care and the extent to which those measures could be used to measure the quality of funded services")
- Sternberg, Steve. 2005. CDC: One million-plus living with HIV. USA Today, 13 June, final edition.
- ¹⁶ Fleming, P. "HIV Prevalence in the U.S. 2000," 9th Conference on Retroviruses and Opportunistic Infections.
- ¹⁷ 2000. Adoption of Protective behaviors among persons with recent HIV infection and diagnosis – Alabama, New Jersey, Tennessee, 1997- 1998. Morbidity and Mortality Weekly Report (49)23; 512-515.
- * The CARE Act reauthorization process was set for every five years beginning in 1990 making 1995 the first targeted year. In 1995, however, Congress was in disagreement over the entire budget for that fiscal year delaying reauthorization of the CARE Act and other programs until 1996. The CARE Act then resumed its previously set five-year calendar, scheduling the next reauthorization for 2000.
- ** The three main classes of antiretroviral drugs are: Nucleoside Reverse Transcriptase Inhibitors, Non-nucleoside Reverse Transcriptase Inhibitors, and Protease Inhibitors.
- *** Research on HIV has developed measurable indicators of the disease's progression, namely CD4 (T-cell) counts, a white blood cell measurement that indicates a strong or weak immune system, and viral load counts, that measure the amount of virus in a person's blood. When the virus proliferates, a person's CD4 count will drop and his/her viral load measurement will rise. As treatment begins to take effect, viral replication slows down, the viral load decreases, and CD4 counts usually rise. These are measurable clinical health outcomes.

Endnotes — Timeline

- ¹ In years 1987 2000, the numbers of AIDS cases were taken from CDC Surveillance Reports. The difference between cumulative (in 1987 and 1990) versus living (1996 and 2000) cases reflects the CDC reporting standard during that time. Surveillance Reports are available online at http://www.cdc.gov/hiv/stats/hasrlink.HTM. The 2005 number was taken from the Kaiser Family Foundation's 2003 estimate.
- ² In 1987 and 1990, AZT was the only available ARV. The 1996 figure comes from multiple HIV treatment experts. The 2000 and 2005 numbers were taken from the ADAP Monitoring Project of each year, which calculates for the previous year (i.e. the 2005 numbers were extrapolated from 2004 data).
- ³ Health Resources Services Administration, HIV/AIDS Bureau. "AIDS Drug Assistance Program Overview." Available online at http://hab.hrsa.gov/tools/adap/adapSecIIChap1.htm. In 1987 and 1990, there was one available ARV. In later years, the term ARV Treatment refers to prescribed treatment regimens consisting of a combination of ARV drugs.
- ⁴ Health Resources Services Administration, HIV/AIDS Bureau. "AIDS Drug Assistance Program Overview." Available online at http://hab.hrsa.gov/tools/adap/adapSecIIChap1.htm. The AZT Assistance Program was the precursor to ADAP.
- ⁵ U.S. Census Bureau, Housing and Household Economic Statistics Division (for all years). Available online at www.census.gov
- ⁶ Karon JM, et al. "Prevalence of HIV infection in the United States, 1984 to 1992." Journal of the American Medical Association 1996;276(2)
- ⁷ Kaiser Family Foundation, Facts on HIV/AIDS: "Paying for New Therapies: The AIDS Drug Assistance Program." March 26, 1996.
- ⁸ ADAP Monitoring Projects, May 1996, May 2001, May 2005. Available online at http://www.kff.org/hivaids.
- Orntrol of Disease Control. U.S. HIV and AIDS cases reported through December 2000, Year-end edition Vol.12. Available online at http://www.cdc.gov/hiv/stats/hasr1202.htm
- ¹⁰ The Centers for Disease Control (CDC) announced this estimate in June. 2005.
- * The CDC did not begin reporting HIV and AIDS cases separately in surveillance reports until 1993. Estimates during 1987 and 1990 were projected, but were later refuted and admittedly too high.
- ** No published information exists on the number of individuals served in 1987 or 1990. The ADAP Monitoring Project, which now reports this information, began in 1996.
- *** In 1990, ADAP was funded as a part of Title II (the specific earmark was initiated in the 1996 reauthorization). No 1990 ADAP spending amount information is available.
- **** Available data on the average costs of HIV medication are conflicting and difficult to assert. The 2000 and 2005 estimates were calculated using data on the July 2005 Average Wholesale Price (AWP) of medications, gauging price increases since June 2003. For each drug and year, the AWP was calculated. The estimates shown here are 80% of the AWP for the ARV treatment regimens that the Department of Health and Human Services recommended as front line and salvage therapies for each year. 80% of the AWP often corresponds to the Average Manufactures Price (AMP), or "baseline" price and is approximately what a third party payer would pay for the drugs. ADAP is able to achieve lower than the AMP prices through government pricing and negotiations with pharmaceutical companies.