

# The AIDS Drug Assistance Program: Securing HIV/AIDS Drugs for the Nation's Poor and Uninsured



## **The AIDS Drug Assistance Program: Securing HIV/AIDS Drugs for the Nation's Poor and Uninsured**

*I'm currently on ADAP; I have been for 13 years. I get switched back and forth between Medicare and ADAP, but ADAP covers the drugs that Medicare and other resources won't cover for me although I can't get pain medication and some antibiotics. ADAP is a good program, they've added medications as the years go by and I'd have to pay a lot to get these drugs if I didn't have ADAP*

MidAtlantic Consumer of ADAP Services

*Given the growth in the number of people who need to get into the ADAP program, maintaining funding remains a huge issue and I am very concerned that state contributions may go backwards.*

Midwestern AIDS Service Provider

*The inner city and rural minority populations most affected by the HIV epidemic are very tough to reach out to. They are traditionally underserved and their priorities often are matters of day to day survival, food and shelter. For women of color family issues have to come ahead of their HIV infection. ... A big answer to making sure that everyone receives the medications that they need is to make ADAP an entitlement program. It has to be something palatable to political will and has to be done right.*

Northeastern ADAP Expert

*Generally people are able to get care through ADAP, but different States have differing eligibility and formulary designs and therefore while some states have an embarrassment of riches, people struggle to qualify for eligibility in other states. Portability might help create a baseline of what's acceptable.*

Pharmaceutical Company Expert

*Talk of Ryan White support services going away is as much a concern as receiving medical care. In some ways the lack of support services is as much a concern as their direct medical care. Without the support of their case manager, some of our clients won't know how to adhere to their medication schedule or they may quit the program. Congress needs to understand that we are now doing a lot more with less and we can't keep it up.*

Plains State HIV/AIDS Service Provider

## **In Memory of Dr. Gene Copello**



**Dr. Gene Copello, Executive Director of the AIDS Institute, passed away on Tuesday, October 7<sup>th</sup>, 2008. The creation of this paper was largely undertaken at his urging. Dr. Copello leaves behind a decades-long record of work on behalf of people living with HIV and worked tirelessly to bring the HIV/AIDS community together. We dedicate this paper to his memory.**

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# **The AIDS Drug Assistance Program: Securing HIV/AIDS Drugs for the Nation's Poor and Uninsured**

## **Executive Summary**

In March, 1987 the Food and Drug Administration approved the use of the very first drug to treat HIV/AIDS. Zidovudine (also known as AZT) was the first anti-retroviral known to specifically act against the HIV virus. At a time when a diagnosis of HIV was viewed as a virtual death sentence, AZT offered hope to many thousands of people. That year Congress rushed to authorize the AZT Drug Reimbursement Program, a “one time” fund that distributed \$30 million in grants to each state over the course of 2 years for the purchase of AZT.

More than 20 years later, there are now 28 lifesaving anti-retroviral drugs that have contributed to the ability of people living with HIV to live longer and healthier lives. The AZT Drug Reimbursement Program was incorporated in 1990 into the Ryan White CARE Act as the AIDS Drug Assistance Program (ADAP). Today ADAP provides not only these life-saving antiretrovirals, but many other drugs that fight opportunistic infections and other medical conditions related to HIV to nearly 150,000 enrollees across 58 States and territories. ADAP has become the safety net program that ensures people living with HIV are able to receive drug treatment throughout the United States. For that reason it is among the most important programs for people living with HIV/AIDS and is a program that has long enjoyed the support of the entire HIV/AIDS community.

As this paper demonstrates, providing medications under ADAP can be a complex task. There are thousands of people in the United States who need medications who are not receiving them, and there are many serious challenges ahead. The AIDS Institute and AIDS Action set out to review the current state of the ADAP program and to offer policy options that might be considered for its improvement. To do so we relied on our organization's own expertise and sought expert opinion through nearly 30 extensive interviews with ADAP consumers, members of the HIV/AIDS community, experts working within the federal and state ADAP programs, representatives from pharmaceutical companies that develop HIV/AIDS drugs, experts from local community and national HIV/AIDS organizations, doctors and other HIV practitioners. AIDS Action and The AIDS Institute agreed not to attribute quotes to specific interviewees in order to achieve greater candor in the interviews. We thank all of the people who responded to our inquiries (see list of people interviewed on page 38).

We offer this policy review so that the President can properly plan for ADAP in future budgets, that Congress can adequately appropriate the necessary funding, and in future consideration by the Congress of the Ryan White HIV Program. We also do so in advance of potential development of a National AIDS Strategy and health care reform. It is an opportunity to remind the people thinking about broader health care issues that people living with HIV are dependent on these programs and that solutions must be found not only to how to maintain not only the current level of treatment and services, but how to improve them and to ensure that all people living with HIV/AIDS are able to receive the treatment and care that they need.

**Carl Schmid**  
Director of Federal Affairs  
The AIDS Institute

**William McColl**  
Political Director  
AIDS Action Foundation

## The AIDS Drug Assistance Program: Securing HIV/AIDS Drugs for the Nation's Poor and Uninsured

The AIDS Drug Assistance Program (ADAP) is successfully providing lifesaving and life-extending medications and other services to over 158,000 low-income and underinsured people living with HIV/AIDS in the US.<sup>1</sup> ADAP is comprised of a total of \$1.4 billion in Fiscal Year (FY) 2007 in both state and federal funding and is the largest component in terms of funding and accounts for more than one-third of the overall funding of its parent program, the Ryan White Program.<sup>2</sup> Approximately one in four HIV positive people in care in the U.S. receive their medications through ADAPs, according to the Health Resources Services Administration (HRSA).<sup>3</sup> In essence, ADAP has become the safety net provider of HIV drugs for people living with HIV in the United States. "Most clients are low-income, with more than four in 10 having incomes at or below 100% of the Federal Poverty Level (FPL was \$10,210 annually for a family of one in 2007), uninsured (69%), and approximately two-thirds are people of color."<sup>4</sup> Consequently, ADAP is among the most important programs for people living with HIV/AIDS.

However, as recently as of February 2006, nine states had waiting lists in which 800 otherwise eligible individuals were unable to access the program solely due to cost controls.<sup>5</sup> Other states had introduced other cost containment measures including lowering eligibility standards or reducing their formulary. These indications were strong enough to lead the authors of the annual National ADAP Monitoring Report to state:

"Waiting lists and other cost containment measures, may, therefore, be semi-permanent features of ADAPs, amidst a growing population of people with HIV/AIDS in need of medications and rising drug costs. Indeed, waiting lists have been documented throughout the course of the National ADAP Monitoring Project and have been present in some states for months if not years. Nationally, at least several hundred people with HIV/AIDS are waiting to obtain medications from ADAPs at any given point in time."<sup>6</sup>

As described in this paper, in just two years the ADAP situation has improved. Pressure on the program eased in FY 2007 as a result of the introduction of Medicare Part D and changes to the Ryan White Program and some other factors.<sup>7</sup> As a result, although it did not last for long, for the first time in recent history of the program waiting lists were virtually eliminated and some cost containment measures were removed by some states.<sup>8</sup> However, as described in this paper, that does not mean that everyone who needs HIV/AIDS medications in this country have them. Despite

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<sup>1</sup> Estimate for fiscal year 2009 from "Budget in Brief Fiscal Year 2009," U.S. Department of Health and Human Services, available at [www.hhs.gov/budget/09budget/2009BudgetInBrief.pdf](http://www.hhs.gov/budget/09budget/2009BudgetInBrief.pdf), p.21.

<sup>2</sup> Carbaugh, Alicia et. al., "National ADAP Monitoring Project Annual Report," *The Henry J. Kaiser Family Foundation and the National Alliance of State and Territorial AIDS Directors*, April 2008 p.1. (referenced as National ADAP Monitoring Project 2008 hereafter).

<sup>3</sup>"Fiscal Year 2009, Health Resources and Services Administration, Justification of Estimates for Appropriations Committees," U.S. Department of Health and Human Services, available at [ftp://ftp.hrsa.gov/about/budgetjustification09.pdf](http://ftp.hrsa.gov/about/budgetjustification09.pdf), p.179.

<sup>4</sup> National ADAP Monitoring Project 2008, p.1.

<sup>5</sup> Kates, Jennifer et. al., "National ADAP Monitoring Project Annual Report," *The Henry J. Kaiser Family Foundation and the National Alliance of State and Territorial AIDS Directors*, March 2006, pp.1.

<sup>6</sup> *Ibid.* pp. 1-2.

<sup>7</sup> National ADAP Monitoring Project 2008, pp.1-2.

<sup>8</sup> *Ibid.* p.9.

improvements to the ADAP program, the United States is among the 45 countries estimated to provide coverage of antiretroviral therapy to just 25- 49 percent of adults and children with advanced HIV who need it.<sup>9</sup> In contrast more 36 countries achieve coverage at a rate of greater than 50%. In part this lack of coverage reflects the lack of access to systemic health care services in the United States. As such it is a broader problem than ADAP is equipped to handle. However it is also an indication of how much more the U.S. must do to achieve coverage.

Moreover, as it becomes clearer that the United States and the world appear headed towards global recession, many advocates are concerned that gains from one time sources of relief could easily be reversed. With declines in State and local revenues and pressure on the federal budget from a faltering economy, ADAPs may not be able to keep up with the growing demand. Already, waiting lists have returned in some states and there are projections for more in the future without increases in funding.

Given the importance of the program to people living with HIV/AIDS, this paper examines the current status of ADAP, provides basic information about the program and reviews the program's current budget and future appropriations needs. It provides ideas and policy options for improvement in advance of the upcoming reauthorizations of the Ryan White CARE Act, the potential for the creation of a National AIDS Strategy and healthcare reform in the United States.

This paper is divided into two major parts. Part I is a Background section on ADAP including an explanation of ADAP, a brief history of the program, and a review of the impact of passage of the Ryan White HIV/AIDS Treatment Modernization Act and Medicare Part D on ADAP. This section is primarily descriptive. Part II, "Future Challenges and Policy Options," reviews trends that have been raised as immediate or potential issues for the program and describes policy options that may help to relieve pressure on ADAP and help plan for the future. Part II is subdivided into four sections: "Program Growth: Longer and Healthier Lives"; "Caps, Eligibility and Formulary Limits: Cost-Containment Measures that Limit Program Effectiveness"; "Service Variability Across Jurisdictions"; and "Other." Each of these sections includes potential solutions to improve ADAP. This paper is meant to be a policy and concept paper and *not* a position paper for the authors' organizations (AIDS Action Foundation and The AIDS Institute).

## **Part I – Background**

### **History:**

On March 20, 1987, the U.S. Food and Drug Administration (FDA) approved AZT, the first anti-retroviral drug to combat HIV. AZT, which is an abbreviation of azidothymidine, interferes with the replication process of HIV. This was an extraordinary breakthrough in the treatment of HIV, the disease that causes AIDS. Prior to the approval of AZT, infection with HIV was effectively a death sentence and AZT provided the first glimmer of hope to people living with HIV that they might prolong their lives. However, although AZT's price was reduced in 1987 from \$10,000 to \$8,000 for a year's supply, the cost was prohibitive to most people living with HIV.<sup>10</sup> As a result,

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<sup>9</sup> "Report on the Global AIDS Epidemic, 2008, Executive Summary" *Joint United Nations Programme on HIV/AIDS (UNAIDS)*, July 2008, p. 26

<sup>10</sup> "AZT's Inhuman Cost," *New York Times (unsigned editorial)*, August 28, 1989

the U.S. government provided a “one time” grant through the Health Resources Services Administration to all 50 states to help purchase AZT for people living with HIV.<sup>11</sup>

This grant program, the “AZT Drug Reimbursement Program,” eventually became the basis for the creation of the “AIDS Drug Assistance Program” which was made a part of the Ryan White CARE Act in 1990. In Fiscal Year (FY) 1996 Congress specifically earmarked ADAP funds to be administered by the states. Since then, all 58 states, territories and the District of Columbia have established an ADAP.

Beginning in 1995, new classes of anti-retroviral drugs for the treatment of HIV were developed. The use of three or more of these drugs in combination (generally referred to as combination antiretroviral therapy or sometimes called “Highly Active Antiretroviral Therapy” or HAART) is the most effective means to reduce the effects of HIV in the body.<sup>12</sup> As the Institute of Medicine stated in 2005, the introduction of HAART fundamentally shifted the delivery of services “from an inpatient hospital and end-of-life social support to outpatient and chronic care.”

In August 2008, the Centers for Disease Control and Prevention (CDC) announced that an estimated 56,300 new HIV infections occur annually in the United States.<sup>13</sup> This number is 40% higher than previous estimates and means there are more people who will require care and treatment than previously believed. The new CDC incidence numbers also revealed that the annual number of new infections has, in fact, been higher than 40,000 for a number of years and has not been that low for some time. The CDC estimates that there are approximately 1.1 million people living with HIV in the United States at the end of 2006.

These improvements in the ability to treat HIV patients, along with the fact that so many people are now living with HIV has resulted in growth in the number of patients eligible for ADAP who need assistance.<sup>14</sup> Ultimately, ADAP is integral to keeping people alive by providing medications that they would not otherwise receive through private or public health insurance or medical assistance programs. ADAP’s growth reflects that the epidemic itself is growing. As a result, ADAP today remains an essential safety net for people living with HIV to attain the lifesaving drugs they need to fight the disease.

### **Structure of the AIDS Drug Assistance Program:**

The ADAP program is administered by the individual States, Territories and the District of Columbia. The States are authorized to provide medications either directly to people living with HIV or through the purchase of insurance, which provides not only medications but general healthcare as well. The medications provided typically include not only antiretrovirals, which work to interfere with the life-cycle of the HIV virus, but also drugs that combat the opportunistic infections associated with an HIV depressed immune system and improve adherence to anti-retroviral regimes (including drugs for substance abuse and mental health).

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<sup>11</sup> Lambert, Bruce, “6,000 AIDS Patients Face Cutoff Of Drug That May Prolong Lives,” *New York Times*, August 24, 1988

<sup>12</sup> Panel on Antiretroviral Guidelines for Adults and Adolescents. Guidelines for the use of antiretroviral agents in HIV-1-infected adults and adolescents. Department of Health and Human Services. January 29, 2008; 1-128. Available at <http://www.aidsinfo.nih.gov/ContentFiles/AdultandAdolescentGL.pdf>. Accessed June 22, 2008.

<sup>13</sup> “HIV Incidence,” *Centers for Disease Control and Prevention*, August, 3, 2008. available online at <http://www.cdc.gov/hiv/topics/surveillance/incidence.htm>.

<sup>14</sup> “FY 2009 Appropriations for Federal HIV/AIDS Programs,” Available from the *AIDS Budget And Appropriations Coalition*, August 18, 2008

Since the Ryan White law provides great discretion to individual states, ADAPs vary considerably in programming, eligibility criteria, drug formularies, number of personnel and the means by which they purchase and distribute drugs. In addition, there is great fragmentation in the U.S. healthcare system and state funding contributions vary widely. States tend to choose how to distribute or allocate HIV/AIDS medications based on the conditions within the state. Typical factors that may influence the decision include the state's HIV incidence rates, available Medicaid coverage, and political support for programs to help people living with HIV. There are essentially three primary methods by which states are able to purchase medications for people living with HIV. These are:

1. *Direct Purchase Model:* Under this model, ADAPs purchase drugs at a discounted price directly from manufacturers or wholesalers. They must then find ways to distribute the drugs either through a state run pharmacy or other distribution program<sup>15</sup> (some states are able to distribute via mail). Discounts are obtained either through direct negotiations or via the 340B Drug Discount Program or Prime Vendor program (which negotiates prices lower than the traditional 340B Program) administered by the Office of Pharmacy Affairs in the Health Resources Services Administration (HRSA). Additionally, Washington D.C.'s ADAP is able to purchase drugs through the Department of Defense allowing it to access low prices available only to large federal agencies (sometimes referred to as the Federal Ceiling Price). As of June 2007, 29 States and territories stated that they used a direct purchase model for the distribution of drugs.<sup>16</sup>

2. *Rebate model:* Under a rebate model, a State or Territorial ADAP typically will pay a pharmacy to handle prescriptions dispensed to the ADAP client and apply to manufacturers for negotiated rebates. The advantage of this system is that ADAPs are not required to directly dispense prescriptions. Additionally rebate funds become available for the purchase of additional drugs (or for use within Part B of the CARE Act).<sup>17</sup> As of June 2007, 24 States and territories stated that they used a direct purchase model for the distribution of drugs.<sup>18</sup>

3. *Insurance coverage:* In addition to providing medications, in FY 2007, 40 State ADAPs paid for insurance coverage for nearly 21,000 people providing not only medications but overall medical health care to people living with HIV/AIDS.<sup>19</sup> Thus, ADAP is allowed to pay not only for medications but for overall health coverage. Currently California, Indiana, Massachusetts, New York and Oregon devote substantial resources to the purchase of insurance, each covering more than 1,000 people living with HIV through the ADAP program.<sup>20</sup> According to HRSA, 6 percent of the total funding the ADAP is spent on the insurance continuation program.<sup>21</sup>

To some extent, states are able to mix and match each of these methods. For example, direct purchase states may also pay pharmacies for the deductibles or co-payments for partially insured

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<sup>15</sup> Chiplin, Alfred and Vicki Gottlich, "AIDS Drug Assistance Programs' Prescription Drug Purchasing: Moving in the Right Direction?," *Center for Medicare Advocacy*, October 21, 2004 available online at [http://www.medicareadvocacy.org/PrescDrugs\\_ADAPandMMAPurchaseOptions.htm](http://www.medicareadvocacy.org/PrescDrugs_ADAPandMMAPurchaseOptions.htm)

<sup>16</sup> National ADAP Monitoring Project 2008, p.86

<sup>17</sup> Chiplin, Alfred and Vicki Gottlich, "AIDS Drug Assistance Programs' Prescription Drug Purchasing: Moving in the Right Direction?," *Center for Medicare Advocacy*, October 21, 2004 available online at [http://www.medicareadvocacy.org/PrescDrugs\\_ADAPandMMAPurchaseOptions.htm](http://www.medicareadvocacy.org/PrescDrugs_ADAPandMMAPurchaseOptions.htm)

<sup>18</sup> National ADAP Monitoring Project 2008, p.86

<sup>19</sup> *Ibid.* p.14

<sup>20</sup> *Ibid.* Chart XXI, pp. 88-89.

<sup>21</sup> "Ryan White HIV/AIDS Program: Annual Data Summary (2006)," Health Resources Services Administration, U.S. Department of Health and Human Services, p.15.

patients and receive rebates on these expenditures. All states have the ability to purchase insurance, but insurance may be too expensive or conflict with other aspects of the state programs and in some states only certain insurance can be purchased (purchasing high-risk pool insurance in some states is not legal, for example). This aspect of ADAP can expand provided there are the necessary funds.

### **Funding of the AIDS Drug Assistance Program:**

ADAP is part of the Ryan White Program, a grant program which provides funds for HIV/AIDS programs and services to cities, States, and service providers. More specifically it sets aside funding used by the states in “Part B” of the Ryan White Program and establishes ADAP, a program “to provide therapeutics to treat HIV disease or prevent the serious deterioration of health arising from HIV disease in eligible individuals, including measures for the prevention and treatment of opportunistic infections.”<sup>22</sup>

The CARE Act is tasked with providing treatment and care as the “payer of last resort,” meaning that CARE Act funds may be used to cover service gaps in public or private health insurance coverage or gaps in public health assistance for HIV services. However, if a person living with HIV is eligible for a covered service via other means such as private insurance, Medicaid or Medicare, then the person should seek reimbursement through that service and Ryan White funds should not be used to pay for that service. ADAP is similarly a “payer of last resort” and therefore a person becomes eligible for funding of medications through ADAP, if he or she is experiencing a gap in funding for HIV/AIDS drugs elsewhere. Currently more than 150,000 people are enrolled in the program.

Overall there is approximately \$1.43 billion in funding for ADAP. Of this, in FY 2008, \$794.4 million was appropriated in federal funding through the Ryan White CARE Act as a set-aside specifically for ADAP. This amount represents more than one-third of the entire federal Ryan White CARE Act’s appropriation (and a little more than half of the ADAP total). This funding is distributed through a formula based on living cases of HIV/AIDS. A small amount of this funding is then set aside for states that demonstrate “severe need” in providing therapeutic drugs to people living with HIV. This set aside, known as the “ADAP supplemental,” increased from 3 % to 5% of funding in the most recent CARE Act reauthorization. In addition to Ryan White funding specifically set aside for ADAP in the CARE Act, Part A and B programs have contributed some additional funding. Two other significant sources of funding for ADAP programs are State funds (\$294 million in FY 2007 – the last year for which an estimate is available) and drug company rebates (\$262.5 million in FY 2007).<sup>23</sup>

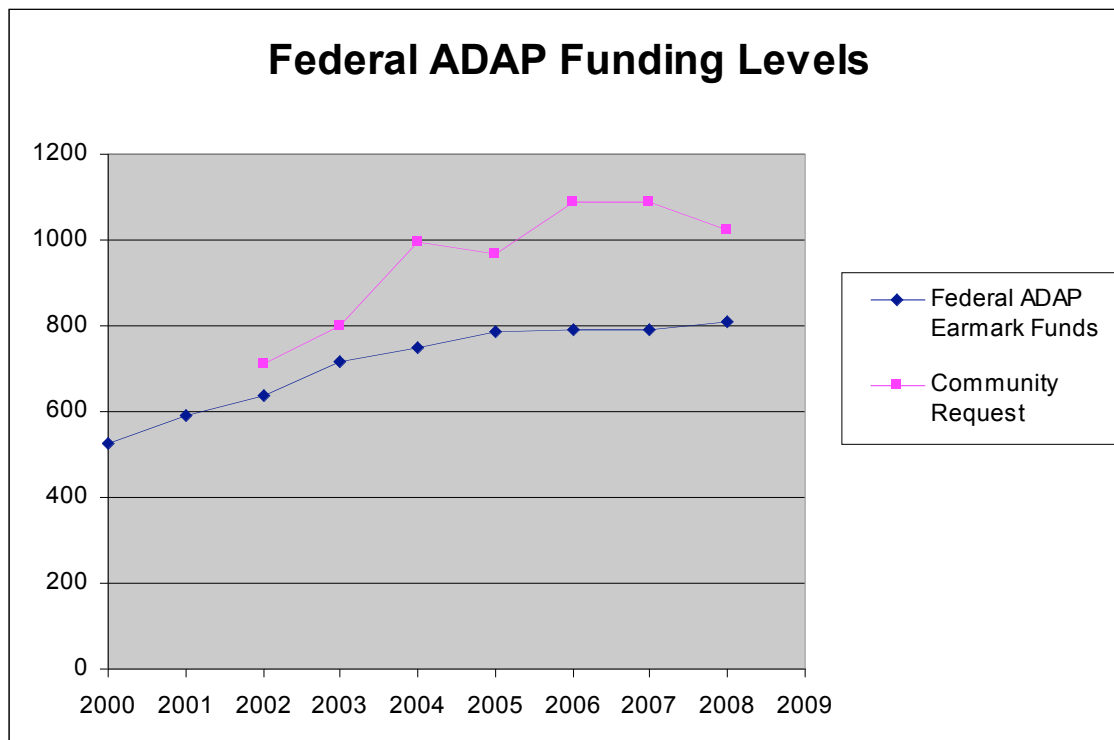
According to NASTAD, there is an annual need for additional funding of approximately \$110 million per year for ADAP, and given shortfalls in previous years, there is a need for an additional \$135 million for FY2009.<sup>24</sup> Currently growth in the federal appropriations has not met the annual need of \$110 million for several years. From FY 2007 to FY 2008 the ADAP set-aside only increased by \$4.8 million and was flat-funded the year before. As the chart below indicates, federal ADAP funding has basically been flat funded for the past 4 years despite increased caseloads and price increases.

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<sup>22</sup> U.S. Code of Law, Title 42 , Chapter 6A , Subchapter XXIV, Part B , Subpart i, section 300ff–26.

<sup>23</sup> National ADAP Monitoring Project 2008, p.11

<sup>24</sup> “FY2009 AIDS Drug Assistance Programs Funding Needs,” *ADAP Coalition*, 2008. Paper available upon request.



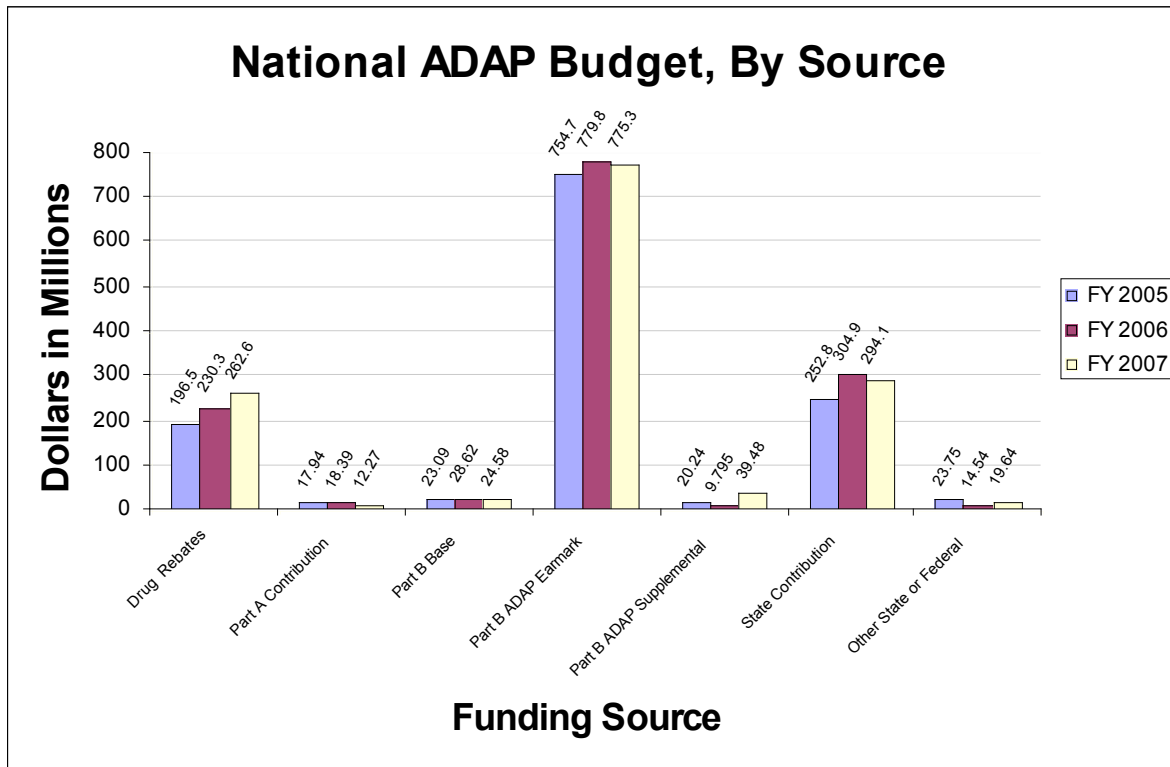
**Chart 1**

In the last year, some ADAPs have been able to deal with the shortfall in funding growth due to distribution changes in the Ryan White Program, taking advantage of the larger ADAP supplemental, and through moving eligible individuals from ADAP to the new Medicare Part D drug benefit. Unfortunately these are one time gains that will not be replicated in the future. Although some states have increased funding to ADAPs, the overall state contribution to ADAP declined by four percent within the last year.<sup>25</sup> Unfortunately more and more states are being hit by budget shortfalls and future growth from the States seems unlikely.

Finally, in recent years the strongest growth in the elements that make up ADAP funding, has been in rebates from drug manufacturers which increased from \$54.5 million in FY 2000 to \$262.6 million in FY 2007<sup>26</sup> (see Chart 2). Unfortunately, since rebates are dependent on factors such as company profitability, negotiations by states and coalitions, and the ability of State ADAP staff to process rebate claims, it is not clear how much additional growth may be available in this sector. Thus all current sources of potential increases seem likely to grow well below the level of funding needed to keep up with growth in the epidemic. To keep up with the expanding need, it is clear that additional funding will be needed.

<sup>25</sup> National ADAP Monitoring Project 2008, p.12

<sup>26</sup> *Ibid.* p.41



**Chart 2**

**Impact of the Ryan White HIV/AIDS Treatment Modernization Act on ADAP:**

In December 2006 the Congress passed and the President signed into law the Ryan White HIV/AIDS Treatment Modernization Act. The Modernization Act reauthorized the Ryan White CARE Act, including ADAP, through September 30, 2009. Subsequently, HRSA began to refer to the reauthorized Ryan White CARE Act as the “Ryan White Program.” Significant programmatic and formula changes were made through this reauthorization, impacting the distribution of Ryan White funds, including ADAP funds. Parts A, B and C grantees are now required to spend 75 percent of their funds on core medical services. The reauthorization increased funding for the ADAP Supplemental and required that every State ADAP must include at least one drug per antiretroviral class and limit the amount of funds carried over year to year. Overall, as described further in this paper, the authors believe the reauthorized Ryan White Program has had a positive impact on the state ADAPs that were experiencing difficulty in providing ADAP medications to beneficiaries in their states.

*Formula Changes:* The new Ryan White law distributes its formula funds, including most ADAP funds, based on both living HIV and AIDS cases reported by name, rather than on a ten year weighted average AIDS only case count, as was the case in the past. Due to this change, funds are distributed in a manner intended to reflect the actual number of people living with HIV/AIDS in a state. This change accounted for some redistribution of ADAP formula funding from state to state. The impact of this redistribution has provided increased funding to some state ADAPs that were experiencing funding shortfalls and have allowed them to increase the number of patients who receive ADAP medications and/or expand the number of drugs on their formularies.

Since ADAP did not receive an appropriation increase in FY07, the change in ADAP grants to each state from FY06 to FY07 are mainly reflective of the changes in the Ryan White law. (A change in

case counts can also account for the change and the total amount available for ADAP formula grants was reduced due to the increase in size of the ADAP supplemental.) As a result of the new law, ADAP formula funding increased in 23 states and decreased in 27, plus in the District of Columbia and Puerto Rico. The largest increase was in Colorado (+\$3.8 million or 67%), while New York lost \$6.6 million. Twenty-two states lost the maximum 5% allowed by the law.<sup>27</sup>

*Increase in Size of ADAP Supplemental Grant:* The new Ryan White law increased the size of the ADAP Supplemental, which is designed to increase ADAP grants to states with struggling ADAPs, from 3% to 5% of the total ADAP Appropriation. Additionally, the new law delinked the ADAP Supplemental from funding the hold harmless provision of the Ryan White Care Act, which historically has decreased the size of the ADAP Supplemental, and changed the eligibility requirements for states to qualify. A waiver for the state match was also instituted. This resulted in an ADAP Supplemental in FY07 that was \$39.5 million or over 300% higher than in FY06.

In FY07, the ADAP Supplemental was awarded to 20 states, Puerto Rico and the Virgin Islands. The highest award went to Texas (\$13 million), while other southern states such as Georgia, North Carolina, Virginia, and South Carolina received the next highest amounts.<sup>28</sup> These five southern states received 75% of the entire ADAP Supplemental. Taking into account both the change in the formula distribution and the changes in the ADAP Supplemental, 31 states received increases in their total ADAP awards and 18, plus DC and Puerto Rico, received decreases. One state's award, Arizona, remained constant.

In the States that did lose ADAP funding, there have been no reports of people losing access to medications or cutbacks in their formularies, with the exception of Puerto Rico which is experiencing unrelated difficulties. In an analysis of the five states that lost the most in federal ADAP set-aside funding both New York and Pennsylvania increased their state contributions by approximately 9% which was not enough to make up the overall shortfall. New Jersey, which lost 5% of its ADAP award, decreased its state contribution by 33% or \$3 million.<sup>29</sup> Therefore, it is likely that other factors such as the impact of Medicare Part D, kept these state ADAPs stabilized.

According to many respondents of the survey conducted by the authors, the increase in the ADAP Supplemental and the changes in the formula distribution, have had a significant positive impact on providing medications to more people. According to one leading national ADAP expert, "overall, the reauthorization has had a positive impact and shifted the money around to states that have a less central epidemic. It has eliminated the waiting lists, raised eligibility levels and allowed states to expand their formularies. We can expect even more improvements in the next year." ADAP providers in North Carolina reported that due to the additional federal funding made available by reauthorization, they were able to increase eligibility from 125% to 250% of Federal Poverty Level (FPL). They are now in the process of raising it again to 300%, while expanding their formulary to include more drugs. One Midwest ADAP Director commented positively on the funding distribution changes, "the money needs to flow with the epidemic." Respondents from some states indicated that the changes in funding distributions did not have any impact on their ADAP.

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<sup>27</sup> Press release, "HHS Awards \$1.1 Billion to Help States, Territories Deliver HIV/AIDS Care," *Health Resources Services Administration*, available at <http://www.hhs.gov/news/press/2007pres/20070405a.html>, April 5, 2007

<sup>28</sup> Press release, "HHS Announces \$42 million for AIDS Medications and Care" *Health Resources Services Administration*, available at <http://newsroom.hrsa.gov/releases/2007/RyanWhitePartsBCD.htm>, September 18, 2007.

<sup>29</sup> Kates, Jennifer et. al., "National ADAP Monitoring Project Annual Report," *The Henry J. Kaiser Family Foundation and the National Alliance of State and Territorial AIDS Directors*, April 2007, Table 18, pp. 82-83

*New Drug Formulary Requirement:* The new Ryan White law requires every ADAP to include at least one drug per antiretroviral class. Since three of the most recently approved antiretrovirals were each in their own drug class, each ADAP was required to add all of these new drugs onto their formularies. The addition of drugs to their formularies could create pressure on some ADAP budgets, but none of the respondents reported difficulties with states meeting this new requirement yet. Since people taking these new medications were most likely already taking medications, the incremental costs may not be great.

*Part B Base Contributions:* During the reauthorization process there was discussion on the role of Part B Base contributions to help shore up struggling ADAPs. Under existing law, states can contribute Part B Base funds to ADAP. As part of the reauthorization, Congress chose to increase funding for Part B Base by \$76 million to help states adjust to the funding changes that resulted from reauthorization while ADAP did not receive any increased funding. The argument was made that states would utilize their Part B Base funds to make up for the ADAP shortfall.

In reality, Part B Base contributions actually decreased by 14% overall, but there were wide differences from state to state. Some states that did not make Part B Base contributions to ADAP in the prior year made sizeable contributions from Part B in FY07. They include Maryland (\$8.2 million); Indiana (\$2.9 million) and South Carolina (\$2 million). Similarly, Wyoming, West Virginia, Georgia, South Dakota, and Alabama increased their Part B Base contributions significantly. Other States dropped their ADAP contributions from Part B Base, including California (\$11.4 million) and Tennessee (\$5.9 million). Approximately half the states did not contribute any funds to ADAP from their Part B Base.<sup>30</sup>

Incidentally, while it was not a major discussion item during reauthorization, Part A contributions to ADAP also dropped in FY07, 33% from \$18.4 million to \$12.3 million.<sup>31</sup> It should be noted that both Part A (urban areas) and Part B (state) funds are provided to each jurisdiction for the purpose of providing primary and support care for HIV/AIDS. A common complaint that interviewees made is that in many States funding for primary care and support services is lacking and that with State funds also falling, it is more difficult for either of these Parts to contribute to State ADAPs.

*Core Medical Services:* The new Ryan White law added a new requirement for Part A, B and C grantees that requires them to spend 75 percent of its funds on core medical services, which include medications. Since medications are part of core medical services and are such a predominant part of Part B, we did not find any states that responded that meeting this requirement was difficult for Part B States.

Some jurisdictions and subgrantees within Part A have reported that they were forced to make cuts to some non-core services which may hinder access to care or medications. Respondents from all over the country emphasized the critical importance for the Ryan White Program to provide the necessary health care and support services to keep people on their medications. The experts interviewed for this paper frequently made statements that, “it is just not the drugs” and how increasingly difficult it is to provide adequate healthcare and support services, whether they are core or non-core medical services.

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<sup>30</sup> National ADAP Monitoring Project 2008, Table 18, pp 82-83

<sup>31</sup> *Ibid.*

*Carry-over Funds Limit/Unobligated Balances Redistribution:* Prior to the current reauthorization of the Ryan White Program, some states did not fully spend their ADAP grant and millions of dollars were returned to the US Treasury at the same time some states were in dire need of additional ADAP funds. The new Ryan White law sought to address this situation by limiting the percentage of carry over funds and instead of any returned funds going to the US Treasury; they would go to the following year's supplemental grant. The impacts of this provision have not yet been realized since it requires two years to assess whether funding should be returned. Many states have reported difficulties in complying with this requirement and have called it too restrictive. The effect of returned ADAP funds would be to increase the size of the ADAP supplemental which would be beneficial to States with weak ADAPs. Policy recommendations on this issue are made below.

### **Impact of Medicare Part D on ADAP:**

The federal government began to provide a prescription medication benefit for Medicare beneficiaries, known as Medicare Part D, in January 2006. Since there are over an estimated 100,000 people with HIV/AIDS who qualify for Medicare either due to their age or disability status, this new drug benefit would have a great impact on many people living with HIV/AIDS. Like other Medicare beneficiaries, the consumer costs are greatly dependant on their level of income level and the plan in which they enroll. With the advent of this new drug benefit, many people who were receiving their medications under ADAP were able to switch to Medicare Part D to receive their medications. This resulted in a cost savings of \$73-\$89 million to the ADAP in FY06.<sup>32</sup>

This cost savings mostly occurred by the states disenrolling from ADAP "dual eligible" beneficiaries (those who qualify for both Medicaid and Medicare), and who have very low incomes. According to the National ADAP Monitoring Report (April 2008), 21 ADAPs did disenroll these beneficiaries. Some states disenrolled beneficiaries from ADAP and put them into their State Pharmaceutical Assistance Programs (SPAP), thus creating additional cost savings to the ADAP. One state ADAP director stated he did not disenroll dual eligible beneficiaries due to complications and lack of a system to ensure continuity in care.

Prior to Medicare Part D, the State of Texas was facing a projected ADAP budget shortfall of \$41 million for FY03-FY07 and had only 40 drugs on its formula. By disenrolling their "dual eligible" clients (those who are eligible for both Medicare and Medicaid) from ADAP, Texas was able to save \$6.8 million in FY06; \$15.2 million in FY07; and is projected to save \$16.4 million in FY08. The state reinvested these cost savings into ADAP and expanded the program.<sup>33</sup>

Since ADAPs are allowed to wrap around the Medicare Part D benefit, and pay such things as premiums, deductibles and co-pays, it also created complicated logistical coordination efforts. According to the National ADAP Monitoring Report, it is estimated that 12% of ADAP clients (17,000 people) are also Medicare eligible.<sup>34</sup> Therefore, states are required to coordinate wraparound payments for each of these individuals to ensure ADAP is the payer of last resort.

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<sup>32</sup> "Safety Net Intersection: AIDS Drug Assistance Programs and the Medicare Prescription Benefit," *National Alliance of State and Territorial AIDS Directors*, 2008, p.7. Paper available upon request.

<sup>33</sup> Statement made by Mr. Dwayne Haught during presentation, "Partnership for Medication Access- Medicare Part D and State Pharmacy Assistance Programs." Session description at [http://www.ryanwhite2008.com/session\\_detail.asp?fseq=114](http://www.ryanwhite2008.com/session_detail.asp?fseq=114)

<sup>34</sup> National ADAP Monitoring Project 2008, p.6

Even though states can wrap around the Medicare Part D benefit, it appears that not all are doing so. According to the Monitoring Report, as of May 2007:

- 20 ADAPs pay Part D premiums
- 25 ADAPs pay Part D deductibles
- 28 ADAPs pay Part D co-payments
- 26 ADAPs pay for medications in the “doughnut hole”

There are likely a number of reasons for this variability; it could be too complicated, not cost-effective, or too costly. Perhaps if the states had more money they would better provide wrap around benefits to their Medicare Part D beneficiaries to reduce peoples’ costs.

For many of the providers, the implementation of Medicare Part D has been “torture”, as one Southern nurse put it. Not only has there been occasional difficulty in ensuring that the CARE Act has remained the payer of last resort, but ensuring coverage and payment from Part D insurers has often been difficult. For example, although HIV antiretrovirals are not subject to prior authorizations, it has not always been the case in reality. Additionally people living with HIV/AIDS may be on many other medications that are subject to prior authorization even if the antiretrovirals are not. While one expert remarked Medicare Part D has had a “tremendous impact” in reducing costs for ADAP, another added that Medicare is going to be an ongoing challenge for State ADAPs since the Medicare drug plans change from year to year.

## **Part II – Future Challenges and Policy Options**

The future challenges and policy options below reflect input from a number of different sources, but most especially the nearly 30 experts on ADAP that the authors interviewed. They are not intended as specific recommendations by The AIDS Institute or AIDS Action but reflect potential changes that should be considered as the President formulates his annual budget, Congress decides on appropriation levels, the Ryan White CARE Act is extended or reauthorized, and as part of conversations about the National AIDS Strategy and health care reform. The policy options are also compiled into a single document in Appendix A of the paper.

### **Factors in Program Growth in State ADAPs:**

*New Medications:* The introduction of new medications at regular intervals has required ADAPs to provide funding for larger and often more expensive formularies. A study in the U.S. and Canada recently found that cocktails of HIV drugs help patients live an average of 13 years longer, if they are able to attain them.<sup>35</sup> A patient who starts taking the drugs at age 20 could expect to live an additional 43 years. Patients who start drug therapy late however, do not live as long as people treated early.<sup>36</sup> According to a paper published in November 2006, the average undiscounted lifetime cost of medical care associated with HIV based on a projected life expectancy of 24.2 years once an HIV-infected person enters care is \$619,000. Of this amount, 73% (\$451,870) is the cost of antiretroviral medications with an additional 5% (\$30,950) spent on other HIV-related medications and laboratory costs. Inpatient and outpatient care costs total 22%.<sup>37</sup>

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<sup>35</sup> Hogg, Robert, et. al. “Life expectancy of individuals on combination antiretroviral therapy in high-income countries: a collaborative analysis of 14 cohort studies,” *The Antiretroviral Therapy Cohort Collaboration, The Lancet*, July 26, 2008; vol. 372: 273-299.

<sup>36</sup> *Ibid.*

<sup>37</sup> Schackman, Bruce R. et. al., “The Lifetime Cost of Current Human Immunodeficiency Virus Care in the United States,” *Medical Care* 44(11):990-997, November 2006

*Treatment Guidelines:* On December 1<sup>st</sup>, 2007 the Department of Health and Human Services released new guidelines changing the timeline on when to begin anti-retroviral therapy. The new guidelines call for treatment to begin when CD4 T-cell counts are below 350 cells/mm<sup>3</sup>.<sup>38</sup> There is also discussion of further lowering the threshold. Although there is some concern that this will result in a new cohort of patients, who need to access therapeutics earlier than expected, most of the experts consulted suggested that it was more likely to result in a gradual increase over time. One expert noted that the decision to begin the use of drugs has generally been based on the experience levels of the physician treating patients and that the decision might depend on a number of factors including the readiness of the client, any substance abuse and mental health issues the client may be facing which could affect compliance with complicated dosing regimens, how they are housed or even the physician's own experience with ARVs. Another issue that may keep physicians from prescribing at a much higher rate is that many of the drugs have side effects (such as increased risk of coronary disease) so there are good reasons to wait. A greater effect is likely from new drugs coming online, the creation of new classes of drugs and updated drugs from older classes.

*Growth in Insurance Costs:* Insurance costs are increasing. In an environment of cost cutting, insurance companies have sought to shift costs to the consumer. Thus some experts have noted that people living with HIV/AIDS who had previously been able to purchase high quality insurance from private insurers and state high risk pools using state ADAP funding had recently been forced to cover high co-pays and co-insurance and had their coverage limited by caps on services.

*Coverage of Additional Services:* In addition to new treatment guidelines, State ADAPs have worked to expand coverage of services related to enhancing the effectiveness of anti-retroviral treatment. For example States ADAPs now seek to include testing and retesting of a patients HIV viral load and CD4 counts (which are indicators of the success of a drug treatment regimen), resistance testing for patients who are beginning new drug treatment regimens to ensure that a particular drug or class of drugs will reduce viral load, and testing and treatments for non-HIV co-occurring illnesses such as Hepatitis C, which may affect the course of treatment success. These necessary, additional services all have the potential to increase costs to State ADAPs.

*New and Increased Testing Programs:* Another factor that is likely to lead to greater demand on State ADAPs is the focus by the Centers for Disease Control and Prevention (CDC) and others on HIV testing to better identify the estimated 231,000 people who are HIV positive who do not know their status.

Identifying people with HIV sooner before they become ill not only serves as a method of prevention, but helps individual's health outcomes if they can access healthcare and medications. What is frequently happening now is that patients who are unaware of their HIV status present themselves for the first time for care and treatment once they become seriously ill. These "late testers" ultimately increases costs for State ADAPS since sicker individuals require more drugs, including both antiretrovirals and drugs for opportunistic infections. Unfortunately they are also often unable to achieve strong clinical results in slowing the infection's effects on the immune system.

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<sup>38</sup> Panel on Antiretroviral Guidelines for Adults and Adolescents. Guidelines for the use of antiretroviral agents in HIV-1-infected adults and adolescents. Department of Health and Human Services. January 29, 2008. Available at <http://www.aidsinfo.nih.gov/ContentFiles/AdultandAdolescentGL.pdf>. Accessed (June 22, 2008) p.12

In September 2006, the CDC issued recommendations that everyone accessing the healthcare system from the age of 13 to 64 be offered a routine HIV test on an opt-out voluntary basis. While this has yet to be fully implemented, increased HIV testing is now beginning to occur in healthcare settings. In a letter from CDC Director Julie Gerberding and HRSA Administrator Elizabeth Duke to Rep. Henry Waxman, Chairman of the House Committee on Oversight and Government Reform (dated September 9, 2008) estimates that of the people who learn their HIV status and will need ongoing care, 25-28 percent will utilize ADAP. Depending on the number of people who test positive, this may result in an extremely large number of new ADAP beneficiaries who will need medications.<sup>39</sup>

In addition to CDC's recommendation for routine opt-out voluntary testing in healthcare settings, the CDC is funding specific programs to increase testing in 25 jurisdictions disproportionately affected by HIV/AIDS. As a result of this effort, the CDC estimates it will identify more than 20,000 additional HIV-infected persons. Using the same percentage referenced above that will utilize ADAP; the CDC estimates 3,333-3,733 infected individuals will utilize ADAP to receive their medications.<sup>40</sup> ADAPs will have to be adequately funded to absorb these new clients.

In addition to CDC testing programs, the Substance Abuse and Mental Health Services Administration (SAMHSA) and the Veterans Administration (VA) are carrying out increased HIV testing, along with numerous state, local and privately funded efforts.

As one Midwest State ADAP Director noted, the increased number of new ADAP patients due to additional HIV testing is a "scary thought." A pharmaceutical company representative said it will create "enormous pressures."

### **Solutions to Costs Generated by Program Growth:**

*Meet Appropriations Need Number:* As shown above, the development of effective antiretroviral treatments has been an astonishing scientific achievement, but it necessarily incurs increased expenses for ADAPs. This factor alone increases the number of people and the length of time that State ADAPs must plan to provide medications for people living with HIV. When coupled with higher CDC estimates of new infection rates, along with new treatment guidelines and additional testing programs designed to find even more people living with HIV, State ADAPs are likely to come under severe funding pressure solely through growth.

Clearly the most important factor in meeting the continued growth in sheer numbers and cost of drugs and insurance is in securing an adequate amount of funding that ADAP needs from federal sources to meet demand. Unfortunately, in recent years, the federal government has failed to appropriate the necessary resources. (See Chart 1 above).

Each year the HIV/AIDS community uses a pharmacoeconomic model to estimate the amount of funding needed to treat ADAP eligible individuals in upcoming federal and state fiscal years. This need number represents the amount of new funding required to allow state ADAPs to provide access to a formulary of HIV/AIDS medications to ADAP clients under the current eligibility rules for each state.

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<sup>39</sup> Letter from CDC Director Julie Gerberding and HRSA Administrator Elizabeth Duke to Rep. Henry Waxman, Chairman of the House Committee on Oversight and Government Reform (dated September 9, 2008)

<sup>40</sup> *Ibid.*

The ADAP federal need number for FY2009 is an increase of \$108.9 million for a total appropriation of \$903.3 million. Coupled with estimated state funding increases, this funding will provide continued services to a total of 126,759 clients in FY2009, including the ability to enroll 8,529 new clients.<sup>41</sup> The ADAP federal need number for FY2010 is an increase of \$269 million for a total appropriation of \$1.084 billion.<sup>42</sup>

For FY09, the Omnibus Appropriation bill provides an increase for ADAP of only \$20.6 million. This is after a FY08 increase of ADAP of only \$4.8 million. Given this estimate, Congressional appropriations for ADAP are far from adequate to meet the growing demand for ADAP and if not corrected soon will result in major consequences to patients. By far, this was the number one suggestion by all the people we spoke with—Congress must increase annual appropriations to ADAP, along with the rest of the Ryan White Program.

- *Policy Option 1: The President should propose and the House and Senate Appropriators must increase funding for ADAP at the level of Need.*

### **Other Factors Affecting Funding for ADAPs:**

*State Contributions:* Many states contribute substantially to the state ADAP program. In FY 2007, state contributions accounted for more than \$294 million or about 21% of the total ADAP budget. This represents a 4% decline from FY 2006. While there are state matching requirements for the ADAP supplemental program (although states can request a waiver), and for higher incidence states for the overall Part B Program, there is no state cash funding match specifically for the ADAP formula award (states can meet their overall Part B match through offering in kind services). Therefore, there is great variation from state to state on the level of state contributions to their ADAP. For example, there are 13 states and the District of Columbia that do not contribute any cash to their state ADAP while 8 others contribute more than 30 percent of the total ADAP budget with state funds (California, Georgia, Idaho, Kansas, Nebraska, Texas, Washington, Wyoming). It is interesting to note that several of these states are low incidence states.<sup>43</sup>

In addition to the economic climate, a state's contribution to the ADAP program may depend on the political climate within the state. States which experienced a large number of HIV infections early in the epidemic, in many cases developed strong advocacy and political support for HIV issues. Other states that are just now experiencing increased infections may still not have the critical mass to generate effective advocacy efforts and may still be experiencing stigma that keeps people from advocating on their own behalf.

When questioned about whether state contributions should be required experts noted that there was a risk as well as a benefit. If a matching requirement is set too high (and too high is different for different states) the states won't make the match and will refuse federal funding. Although one community activist said that there would be a high price to pay if that were to occur in this day and age and predicted it would never happen. Additionally setting the requirement too low might increase the requirements in some states, but might cause other states that now donate at a higher level to lower their contribution.

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<sup>41</sup>“ADAP Budget Projection - Fiscal Year 2009,” National Alliance of State and Territorial AIDS Directors, p.1

<sup>42</sup>“ADAP Budget Projection-Fiscal Year 2010,” *The ADAP Coalition*, available upon request.

<sup>43</sup>National ADAP Monitoring Project 2008, pp. 16-17

One large state ADAP Director said, “the state match has served us well, and helped us get state money, but when there is a budget crisis, the governor doesn’t care. Requiring a state match could help, but in some states who say they won’t contribute, it could back fire.” When asked if the current state requirements are adequate, one Midwestern State ADAP Director simply stated, “not at all”. Another large state ADAP director said the state matching requirements need to change and there should be a specific match just for ADAP and not just for the overall Part B program.

One expert on the national ADAP program noted that Congress set the supplemental program in a way that states with the greatest need also must bear the heaviest burden and provide a match while states with less burden are not required to make such a match. One issue is that the reasons why a state may or may not decide to match are strongly variable and it is a concern that people should not be penalized solely based on where they live. One final concern raised by a community expert is that states that are required to match federal funding will take funds from another needed state program such as an HIV prevention program to move them into the State ADAP.

With the nationwide economic downturn and so many state budgets facing severe constraints, including some of the largest state ADAPs such as New York, California, and Florida, there is a growing concern that state contributions to ADAP will be cut. The National Conference of State Legislatures reported in July 2008 that states in this fiscal year are facing a \$40 billion budget shortfall, three times higher than the previous year, and are forcing states to cut spending and jobs.<sup>44</sup> The Center on Budget and Policy Priorities estimated in November 2008 that at least 41 states faced or are facing shortfalls in their budgets for this and/or next year and the budget gaps that will need to be closed in the coming fiscal year could be in the range of \$100 billion or more.<sup>45</sup> Without adequate increases from the federal government, ADAP budgets will be facing even a more heightened crisis.

- *Policy Option 2: Review State contributions and work with state activists to encourage individual states that make little or no contribution to begin doing so.*
- *Policy Option 3: Review current state match requirements and suggest legislative changes that require states to match at some level federal ADAP spending with state spending.*

*Insurance coverage:* As noted above, 40 State ADAPs pay for insurance coverage which helps to alleviate the cost to the individual to maintain access to medical care in addition to access to drug therapy. Although cost can be a factor in making this decision, the potential to extend access to services not covered by ADAP is particularly desirable. As a result State ADAPs should be encouraged to consider expanding access to insurance.

- *Policy Option 4: States should be encouraged to use the insurance option where possible. Congress should review mechanisms to expand full insurance coverage for people who are eligible for ADAP.*

*Price Negotiations:* There are two organizations that negotiate with companies to influence prices for HIV/AIDS drugs. The Fair Pricing Coalition is an ad hoc organization of HIV/AIDS organizations and activists that seeks to set the initial price of HIV drugs. In their own words, “The

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<sup>44</sup> Press Release, NCSL News “What a Difference a Year Makes: More States are Facing Budget Woes,” *National Conference of State Legislatures*, July 23, 2008

<sup>45</sup> McNichol, Elizabeth and Iris Law, “State Budget Troubles Worsen,” Center for Budget and Policy Priorities, available at <http://www.cbpp.org/9-8-08sfp.htm>, November 12, 2008.

overall goal of the Fair Pricing Coalition is to stop the upward creep in the cost of drugs. This means negotiating for prices for new drugs that are truly “cost neutral,” meaning that they will not increase the net cost of treatment. Over the longer term, the Fair Pricing Coalition fights to lower the cost of treatment by reducing the cost of drugs.<sup>46</sup> The focus on initial cost allows other organizations to continue negotiations at a lower level.

The ADAP Crisis Task Force (ACTF) consists of a group of state AIDS directors and ADAP coordinators, who convene negotiating sessions with the eight drug companies that manufacture antiretrovirals. These negotiations were first convened in March 2003. Negotiated prices are available to all State and Territorial ADAPs. Although pricing information is confidential, the authors of this paper have been told that in all cases, ACTF negotiated pricing is below the pricing mandated by the 340B legislation, and in some cases ACTF’s HIV/AIDS drug discounts approach or exceed negotiated federal levels.

As noted above, a number of states continue to rely on rebates to achieve greater savings on costs. Rebates increased from 6% of the ADAP total budget to 18% between FY 1996 and FY 2007 and were the largest source of growth in ADAP in FY 2007. The most recent reauthorization of the CARE Act requires that rebate funds be returned directly to Part B programs. This allows Part B grantees to use funds for services other than medications, but they are also free to allocate rebates back to ADAP programs as needed. One issue is that pursuing all rebates from drug companies may become administratively burdensome and States must be careful to ensure that they apply for rebates.

- *Policy Option 5: In accordance with current federal statute, (Veteran’s Health Care Act), maintain the current price negotiation methods with individual pharmaceutical companies described above.*
- *Policy Option 6: Allow all State ADAPs to have access to funding negotiated by the Department of Defense as is currently allowed by Washington D.C. if it is lower than the negotiated price.*

*Medicare Part D: ADAP and True Out Of Pocket Costs:* As noted above in the Section on Medicare Part D, if State ADAPs were able to count ADAP expenditures toward “True Out Of Pocket” (TrOOP) costs, more states would be able to provide additional medications for more people. States are currently allowed to pay the costs but such costs don’t count towards the beneficiary’s cost in determining their TrOOP. As a consequence, they are unable to escape from planned payments prior to reaching Medicare Part D’s catastrophic coverage (known as the “doughnut hole”). Allowing such costs to count would result in an estimated cost savings to ADAPs of \$25-44 million per year to the national ADAP budget.<sup>47</sup> One large state AIDS Director said “once Medicare Part D got implemented it helped stabilize our ADAP, it even gave them a surplus.” If ADAP expenditures were able to count as TrOOP, “it would shift several hundred clients and help keep people on our [ADAP] rolls.”

- *Policy Option 7: Change the Medicare law or the interpretation of the current law so that ADAP expenditures will count as TrOOP.*

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<sup>46</sup> Dalton, Paul and Lynda Dee. Press Release: “Fair Pricing Coalition Slams Bristol-Myers Squibb over Drug Price Increases,” San Francisco, CA and Baltimore, MD, January 15, 2008:

<sup>47</sup> “FY2009 ADAP Funding Need Pharmacoeconomic Model: Questions and Answers,” National Alliance of State and Territorial AIDS Directors, p.5.

- *Policy Option 8: Encourage States to ensure that their State ADAPs pay for beneficiary costs in the “donut hole” along with other Medicare wrap-around costs.*

*State Pharmacy Assistance Programs (SPAP) for HIV/AIDS Beneficiaries:* Some states, in order to get around the fact that ADAP expenditures do not count toward TrOOP, have created SPAPs for Medicare beneficiaries who have HIV/AIDS. Unlike ADAP expenditures, SPAP expenditures do count toward TrOOP. States such as Illinois, Texas, and Virginia have successfully created HIV/AIDS SPAPs and have resulted in millions of dollars of cost savings to ADAP programs. It should be noted that there are significant barriers to creating SPAPs. SPAPs require state funds to be specifically appropriated for the creation of an SPAP, a task that will be very difficult in the current fiscal climate. Additionally SPAPs require a separate and duplicative administrative and operational structure from ADAP – adding cost and complexity. Thus the priority is to have ADAP expenditures count toward TrOOP, per Policy Option 7. Nevertheless in the absence of reform on TrOOP, States may wish to explore the creation of an SPAP.

- *Policy Option 9: Encourage states to investigate if the creation of SPAPs for HIV/AIDS beneficiaries is feasible and would result in cost savings to ADAP in their state. HRSA and CMS can provide technical assistance in the creation of SPAPs.*

*Medicaid Expansion:* Just as Medicare Part D created a cost shift by moving people off of ADAP, passage of the Early Treatment for HIV Act (ETHA) would create another significant cost shift. Since ADAP is funded primarily through federal appropriated dollars, and increases into the program have been negligible in recent years, transferring ADAP clients to entitlement programs, such as Medicare and Medicaid, would greatly enhance the state of many ADAPs.

ETHA would allow states the option to cover under their Medicaid program people who are HIV positive, rather than wait until they are fully disabled with AIDS. This would provide health care and treatment for our Nation’s poor before they become very ill. This would not only be the compassionate and ethical thing to do, but it is also cost-effective.

Since ADAP is currently paying for the prescription costs for many of these low-income HIV-positive people, since they can not qualify for Medicaid, allowing states to cover them on their Medicaid program would transfer many people off ADAP. There are pending bills before both the House and Senate and there have been efforts to pass a \$500 million ETHA demonstration project.

One large state AIDS director said that if ETHA passed, “it would help and affect thousands of people.” In dissent one commenter stated that if ETHA passed there would be a question as to whether states would implement it due to affordability.

- *Policy Option 10: Congress should pass the Early Treatment for HIV Act (ETHA) while ensuring access to social support services continue and that States have enough incentive to implement it. Advocates for the change must then work at the state level to ensure that states alter their Medicaid programs to allow income-eligible person living with HIV to enroll.*

*Transformation of the ADAP Program into an Entitlement.* As the Institute of Medicine (IOM) noted in “Public Financing of HIV/AIDS Care; Securing the Legacy of Ryan White,” the course of HIV disease has changed and people living with HIV in many cases now “require care that is

appropriate for a chronic illness rather than for an acute terminal illness.”<sup>48</sup> As the IOM stated, “HIV is a complex, multi-system illness that is heavily influenced by other aspects of the individual;”<sup>49</sup> thus, in addition to medical treatment supportive services such as substance abuse, mental health and nutrition services are increasingly needed as patients live longer and require chronic care. Highly Active Anti-Retroviral Therapy (HAART) became (and remains) the standard of care for HIV with a need for adherence rates of 90 percent or higher. Access to medications is therefore critical.

The IOM additionally highlighted fragmentation of the U.S. Medical care system, noting that a substantial portion of people living with HIV were uninsured or underinsured making the Ryan White CARE Act (and ADAP) a substantial source of funding for coverage. As a result of their review the IOM recommended that “the federal government should establish and fully fund a new entitlement program for the treatment of low-income individuals with HIV that is administered at the state level.”<sup>50</sup> This recommendation also makes sense within the narrower issue of ensuring delivery of HIV medications to people who need it. Given these twin challenges of treating HIV and fragmentation of the system several of the survey’s respondents noted that it is time to achieve a more enduring model of HIV care and services.

- *Policy Option 11: Transform the ADAP Program, along with other Ryan White services, into an entitlement program for people living with HIV/AIDS*

### **Limitations on Access to the Program:**

*Need for access to medications:* The IOM also estimated that more than 230,000 people required access to but are not receiving “Highly Active Antiretroviral Therapy” (HAART) which is the standard of care for the treatment of HIV.<sup>51</sup> Although this estimate took place in 2005 and therefore was unable to take into account implementation of the new Medicare Part D law or the potential new estimates of the number of new infections each year by the CDC (see above) this estimate is likely to be an undercount of the number of individuals who require medication for HIV. According to the IOM, barriers to receiving care, and consequently to gaining access to the drugs needed for care include lack of insurance, lack of supportive services including case management, lack of basic amenities such as food, housing, transportation, inability to use sick days, and comorbid illness including mental health, substance abuse and other issues.<sup>52</sup>

Some of the experts surveyed by the authors estimated that up to 40% of people living with HIV who should be receiving medications in the US are not, often because they are unaware of their HIV positive status or they do not know how to access services. Even experts in the states that report having enough ADAP funds to meet current needs say that not everyone in their jurisdiction who needs HIV drugs is receiving them. At least three of the experts consulted expressed a desire for ADAP to be allowed to spend more money on medication adherence and client outreach and case finding.

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<sup>48</sup> Committee on Public Financing and Delivery of HIV Care, “Public Financing and Delivery of HIV/AIDS Care: Securing the Legacy of Ryan White,” *Institute of Medicine of the National Academies*, 2005, p.6.

<sup>49</sup> *Ibid.* p.10

<sup>50</sup> *Ibid.* p.17

<sup>51</sup> *Ibid.* p. 181.

<sup>52</sup> *Ibid.* pp. 129-131.

- *Policy Option 12: Increase flexibility to allow ADAPs to spend funds on adherence services and outreach to individuals who are not currently accessing care.*
- *Policy Option 13: Increase the flexibility and availability of Minority AIDS Initiative funds to allow greater spending on ADAP. Such funds are the only ADAP funds used for outreach.*

The experts also often mentioned the impact of a lack of support and care services on the future of ADAP. In fact, during the course of the interviews, more people tended to say that the fundamental basis of ADAP is fine, but that the problem has now also shifted to problems in attaining primary care and that one barrier was the lack of support services. Ironically, one expert's perception was that this change was partly driven by the Institute of Medicine study cited above which placed less emphasis on support services. The expert states, "... in a lot of places some of those support services were critical. Some communities were doing well, but many were not.

In the course of conversations, experts stated that there was a lack of funding for: insurance continuation, transportation, housing, dental services, medications and services for substance abuse and mental health, Hepatitis C drugs (on ADAP formularies), outreach, services for older populations, adherence counselors, treatment education

A continual issue is that barriers to receiving medications and care extend far beyond simply receiving a diagnosis and receiving medications. As one expert noted, these are tough populations to reach out to. The epidemic is found in traditionally underserved communities including inner city and rural minority communities. The primary issues for people who are poor may simply include day to day survival including food and shelter. Many women of color who are becoming infected at an increased rate must prioritize family issues such as getting a child food or services over their own health.

- *Policy Option 14: Congress must ensure that funding for all Parts of the CARE Act beyond ADAP and other healthcare programs meets the full need of providing treatment and care including ensuring that all people who know that they are HIV-positive are able to receive high quality treatment and care including supportive services.*

*State Service Variability and Cost Containment Measures Affect the Provision of Services:* Perhaps the most notable feature of the ADAP program is that each state's program is a mixture of a number of factors that are often unique to the state. As one expert on state ADAPs noted, a State's ADAP program is essentially dependent on matching the program to a puzzle of its healthcare environment and political climate. The gap between Medicaid and private insurance in the states may be the most important piece. Size is important as well, since federal ADAP earmark funding allocations are tied to the size of a state's HIV epidemic.

However states also may manage to reach an economy of scale at a certain point. A state with a large population of people living with HIV may have enough resources to have networked and linked computers with its own special ADAP program which allows a number of people to be processed quickly and efficiently. In contrast a state with a small population may have just one person in charge of ADAP and that person may also be in charge of all other sexually transmitted infection programs and the state's bio-terror response. In such states the loss of institutional memory may be a problem when knowledgeable individuals move to other employment.

As one leading ADAP expert commented, "ADAP operates state by state and they are individual, diverse programs. Every ADAP is different since it is tailored to the state need and available

resources.” While the federal government provides the majority of the funds to each state, there are other factors that lead to the diversity in each state ADAP.

One large state AIDS director said that its ADAP has grown remarkably since the advent of AZT. “We are able to cover everyone under 300% of federal poverty level and have a surplus and thinking of expanding our eligibility. But people are falling through the cracks and depending on the state, the number of drugs and income eligibility are not adequate. It is not a perfect system for everyone...and we must have increased funding every year in order to meet the growing demand and price increases.”

One pharmaceutical company representative noted ADAP is largely left to the states and depending on where you live determines what drugs you receive. For example many states do not cover Hepatitis C treatment and do not cover certain diagnostic tests. She also commented that income eligibility requirements are too restrictive. Several others echoed this view and complained about the lack of coverage in some states for medications, particularly mental health and substance abuse drugs, diagnostic tests and vaccines.

State ADAPs have traditionally relied on a variety of means to slow or stop spending when they have reached the limits of available funding. States have often resorted to capping program enrollment resulting in wait-listing individuals for access to services. As noted above, in February 2006 approximately 800 people were waitlisted for ADAP services.

Similarly states may set eligibility requirements lower to avoid excess costs. Typically states set eligibility in relationship to the federal poverty level although some states may set medical eligibility requirements (level of CD4 cells) as well. Currently nine states set eligibility requirement at 200% while nine states set it at approximately 500%. Currently there are no federal criteria for eligibility other than that clients of state ADAPs must be HIV-positive and low-income.

Likewise, ADAP formularies are set by the state, as they are in Medicaid. Typically states have made decisions about including drugs based on a combination of review of FDA approved drugs, PHS guidelines, cost and in some states recommendations from a board of medical practitioners. Most states have now covered all antiretrovirals, at least in part as a response to the new requirement in the Ryan White CARE Act that at least one drug from each class of drugs be included in the formulary. However there is considerable variation among other classes of medications including drugs for the treatment and prevention of opportunistic infections, along with drugs for side effects of antiretrovirals, and that assist with adherence issues such as drugs for substance abuse and major psychiatric disorders.

One issue that has been raised by people living with HIV is that having attained ADAP benefits in one state, due to the varying eligibility requirements, it may not be possible for them to move to another state either to attain care, move in with family or to move for a job. In fact one expert pointed out that the issues of portability is beyond just moving state to state. In a natural disaster like hurricane Katrina which occurred in 2005, there are extraordinary difficulties in ensuring that people get access to needed healthcare when systems are down and don't talk with each other in any case.

Other experts disagreed that portability was a particular problem. For one thing, the U.S. healthcare system by and large is not portable with the exception of national programs like Medicare and the Veterans Administration. Medicaid, for example, is set via state requirements and benefits are not

transportable to another state. Ryan White is the safety net beneath the nation's more comprehensive safety net of Medicaid. Therefore, some of the variability in ADAPs is due to the difference in services they have to provide due to a lack of Medicaid coverage. In this expert's opinion seeking or applying for insurance is just one more thing to do when someone relocates.

In general experts suggested that alleviating differences between eligibility requirements and formulary variables would tend to create a level of portability. One expert stated with regards to the formulary that, "requiring all approved classes is a reasonable expectation." However that same expert noted that standardized eligibility would be problematic since different states have differing resources.

When asked if there should be minimum formulary and standardized eligibility requirements, another expert noted that the impact on each state system would be different. For example a rebate model system might be disadvantaged if new clients moved into the state requiring greater costs. This expert believes that portability is an issue, but that it can only be achieved if ADAP is made into an entitlement program.

One idea would be to create a demonstration project of 5 geographically connected states to work out care systems within a small framework. Such an experiment does have the potential to be quite complex. In addition to establishing a minimum formulary and income eligibility level, it would need to create a distribution formula with multiple factors such as state Medicaid eligibility and coverage, the availability of private insurance coverage or high risk pools and state contributions while not creating disincentives to state funding. It would also need to ensure that each state receives an equitable share of funding and does not force State ADAPs to create new waiting lists or otherwise limit services.

- *Policy Option 15: Alleviate state variation by requiring states to set a floor for eligibility of 350% of the federal poverty level*
- *Policy Option 16: Require a stronger formulary that includes all antiretrovirals and drugs for opportunistic infections.*
- *Policy Option 17: Create greater portability by ensuring that beneficiaries receive comparable medications, services and programming in each State.*

*Distribution of Funds:* Currently 95% of ADAP funds are distributed based on current HIV and AIDS case counts. The remaining 5% in the ADAP Supplemental is for states that have struggling ADAPs. The recent reauthorization appears to have readjusted the funding distribution in such a way to improve access to medications for more people. While increased appropriations for ADAP will be the driving force in providing ADAP medications to low-income people, there may be some other adjustments in the Ryan White law that can help improve access to medications.

While there was some redistribution in funds as a result of the new Ryan White law, in an attempt to not destabilize existing funding systems, no state lost more than 5% of its formula funds in FY07 due to a hold harmless provision. Additionally, the law provides that all states must receive 100% of their FY07 award in FY08 and FY09. Due to this protection, without increased appropriations, the ADAP awards for these years will be held relatively constant.

In fact, that is what occurred in FY08. ADAP received only a minor increase of \$4.8 million in appropriations. When the awards were distributed, not one state or territory received an increase in its ADAP formula funding, and 25 states and territories received very slight decreases, and 34

received 100% of their FY07 formula award.<sup>53</sup> As a result, with higher caseloads it will be increasing difficult for many states to provide more people with medications without funding increases.

If there was not a hold harmless provision it might be possible for some states to increase their ADAP enrollment, but the impact on states losing funding would also have to be considered. The reason why states would lose funding would be due to their lower HIV/AIDS case counts compared to other areas so perhaps when it comes to ADAP the impact of removing the hold harmless would not be that great. One state representative whose state benefits from the hold harmless voiced support for ending the hold harmless so that more people could receive ADAP. However, there are strong competing voices to continue the hold harmless provision.

The increase in the ADAP Supplemental has clearly helped some states with weak ADAPs. The issue has been raised whether the states receiving these funds may grow reliant on this increased funding and may purposely not bolster their ADAP with state or Part B Base funds to ensure they qualify for the Supplemental. A review of the states that received significant Supplemental ADAP increases in FY07 showed no clear pattern. Some states reduced their state contribution to ADAP, while others increased their contribution. This issue will have to be monitored and analyzed in the future as more years go by.

Another proposal that can be considered is to distribute Ryan White funds not based solely on HIV and AIDS case counts, but on a different formula that considers the severity of need in that area. The current formula distribution may not be the best way to provide the most people with ADAP medications in the country. Since some states do not utilize their full ADAP award and other states are in desperate need of additional funds, perhaps there is a different manner that the funds can be distributed and more people can receive ADAP medications.

The current distribution formula does not consider the number of people utilizing ADAP. Two areas may have the same number of HIV/AIDS cases, but in one jurisdiction there may be a higher level of people with health insurance than the other and therefore, there may not be as great a need for ADAP as in an area that has more people in poverty and lacking health insurance. The current Ryan White law directs HHS to consider and construct a Severity of Need Index to distribute Ryan White funds. HHS has proposed such a system for comment, but it is currently directly to Part A, although HHS had indicated they will next examine a SONI for Part B as well.

There was a wide variation in the response from the people we interviewed on whether they thought ADAP should be distributed in a different fashion. Some people believed the current system should remain the same. Representatives from a national organization with expert knowledge of ADAP said it would be very difficult to devise a system that does not take into account state Medicaid contributions, which they do not want considered since it would penalize states for investing in their state's healthcare financing. As a note, the current SONI HHS has constructed does not consider state Medicaid contributions.

A national ADAP expert said he was "skeptical of a SONI and there are no measurable statistics that can be used for formulating one for ADAP....I think the system we use today looks fine, with some changes." Similarly, A large state ADAP director voiced support for continuing the current

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<sup>53</sup>Internal analysis by The AIDS Institute based on News Release, "HHS Awards \$1.1 Billion for HIV/AIDS Care, Medications," U.S. Department of Health and Human Services, April 4, 2008.

system based on caseload and commented, “we should just increase the pie and not create winners and losers...creating a SONI would provide disincentives to the states.”

In contrast, another large state AIDS Director voiced support for it, but questioned how it would be put together. A representative from a jurisdiction that does provide strong local funding voiced support for changing the current system. He voiced support for distributing the funds based on need, including the level of poverty, and number of ADAP beneficiaries in a jurisdiction. He believes the SONI can be applied for ADAP.

One provider in the South said the funds should be distributed based on “who is the sickest and consider such factors as T-cell count, entry into care, death rate, along with the poverty rate... but there should be a hold harmless.” Finally, a national ADAP expert voiced support for SONI but added, “we will never reach agreement on it.”

One pharmaceutical representative suggested that the funds be distributed based on the number of people in care, not by their case count, and reward jurisdictions for bringing people into care and treatment. “The current system rewards jurisdictions equally whether they serve people or not. We need to link people into care, and reward them with incentives for case finding and ensuring adherence to care.” The representative further said the current Ryan White structure is too complex and needs to be simplified with fewer parts.

- *Policy Option 18: Remove the hold harmless provision while increasing appropriations or keep hold harmless at an amount less than 100%, at either 95%, 90% or below per year.*
- *Policy Option 19: Allow HRSA to continue to develop a Severity of Need Index for ADAP however they should not implement such a system without authorization and funding from the next President and Congress.*
- *Policy Option 20: HRSA currently has the authority to reexamine ADAP Supplemental criteria on an annual basis to set eligibility. Using a transparent process, they should conduct an annual review process to ensure that State ADAPs are able to meet the need for therapeutic drugs.*

#### **Assistance Programs, Research and Other Issues:**

*Patient Assistance Programs: When ADAP and other sources of medication are unavailable for needed drugs for low income people living with HIV, private pharmaceutical companies have often created programs to help provide specific drugs to patients. Unfortunately, there is little nationwide data since each company maintains its own program and keeps it confidential. In reality these programs have proven to be very important and companies have proven willing to work with ADAPs to help individuals access the program.*

Nevertheless, relying on pharmaceutical corporations for providing these drugs however has significant drawbacks. In general, drug companies will not discuss or coordinate their patient assistance program eligibility requirements or procedures with other drug companies due to concerns that such discussion will be viewed as “collusion” and violate federal anti-trust laws. This prevents the establishment of uniform forms and procedures resulting in each company having its own process. As a result, management of these cases is very burdensome. Each patient may have to process applications with multiple companies and are generally required to renew at regular intervals, typically every few months.

For Ryan White and ADAP grantees that seek help from the pharmaceutical companies for individual patients, this can be a huge drain on case management services. As would be expected from a private individualized system, there is a far less systematic approach than is needed when dealing with a large patient population. In reality, these programs are meant solely as a temporary fallback and should not be relied upon as a major source of medications for the U.S. It would be much better to find ways to ensure that all people living with HIV are able to access insurance or a program that provides medications.

- *Policy Option 21: Congress should investigate the number of patients who are being covered by Patient Assistance Programs and increase appropriation levels to adequately cover these patients through ADAP or other funding mechanisms.*

*Limited New Drugs and Research:* Almost every respondent expressed concerns about the future since the need for ADAP medications continues to grow and there is a constant need for increased funding. “ADAP is basically meeting the needs of most people today within the bounds of its current funding, but there is a need every year for more money. Without it, we will be dealing with a crisis situation. ... The program has maintained stability in recent years due to increased state contributions,” commented one national leading ADAP expert.

Since August 2007, four important antiretroviral drugs have been approved for use against the HIV virus by the FDA. These include two drugs which are in entirely new classes of antiretrovirals and which offer additional therapeutic options for people living with HIV who have become resistant to more common drug combinations. There appears to be some progress in combining current drugs into all-in-one combination pills and treatment refinements of recently released drugs. However, patent issues and the need for cooperation among drug companies make the prospects for new combination therapies slower in the United States than in the rest of the world.

Unfortunately there are currently very few promising antiretroviral HIV drugs in the development pipeline that appear likely to emerge before 2010. Additionally there is competitive pressure on drug companies to ensure strong profitability with new drugs. Unfortunately with a currently strong HIV market and little prospect of a “blockbuster,” some drug companies are beginning to lose the incentive to continue development. At least one drug company (Roche) has decided to end its involvement with HIV. There is better news for co-occurring disorders including Hepatitis B and C and tuberculosis. Nevertheless there is a clear need to reinvigorate the HIV therapy pipeline.

- *Policy Option 22: Congress should adopt policies that continue to help private companies to invest in research and develop new drug therapies.*

*Changes to the Unobligated Balances Rule:* As noted above in the Section on changes to the Ryan White Program, the new law limits the percentage of unobligated funds that a state may maintain

from year to year. Some of the State officials we spoke to stated this new carry over limit was posing difficulties for them. One State Director said, “it would be tough to meet the requirement, but to spend the funds we are making more drugs available and spending money on other things such as outreach.” One national ADAP expert commented that this new requirement “would not be so difficult for the direct purchase states since they can plan ahead and buy drugs. However, for those state that use the rebate model and are reimbursed, it may be more difficult.”

One large state ADAP director called the provision “very problematic and incentivizes expenditures of bad things. With so many contracts it is very hard to reach the 2% level.” He recommended that perhaps it be changed to 5%. The HIV community has yet to see the impact of this provision. If some states have difficulty in spending its ADAP funds and have to return some funds, it may be beneficial to other states that are in need of the money. If this does occur we can see more people access medications.

Confounding the situation, HRSA is requiring states to treat rebate dollars as income and therefore, under OMB regulations, they must spend these rebate dollars first. This may make it harder for some states to spend all their ADAP money. A waiver from this requirement, which may take the form of a legislative change, is being sought.

- *Policy Option 23: Require HRSA to review the current policy on unobligated fund to determine whether which jurisdictions, if any, have lost funding and to report back to Congress with possible solutions or changes.*
- *Policy Option 24: Change the funding amount that may remain unobligated from 2% to 5% and relax one or both of the penalties for not complying with the unobligated funding requirement.*
- *Policy Option 25: HRSA should review and change requirements so that rebate income is not considered to be program income and may therefore accrue after a grant year has ended. If HRSA fails to act, Congress should clearly state that ADAP funds are exempt from policies requiring ADAP rebate dollars to be expended before federal funds.*

### **Conclusion:**

The United States is currently coming to terms with fragmentation within the health care system and the necessity to provide health care for millions of people who do not currently have access to private or public health care programs. Advancement in treatment for HIV disease has meant that people have the potential to live longer, healthier and more productive lives. However, these gains are at least partially dependent on the ability to diagnose HIV early and to ensure ongoing treatment and access to needed drugs.

Importantly, the AIDS Drug Assistance Program has made major gains in the last 2 years after reauthorization of the Ryan White CARE Act and the introduction of Medicare Part D. However, a realistic view must take into account that the ending of the waiting lists and improvements in formularies and eligibility standards were created at least in part due to the gains from Medicare Part D, changes to the ADAP supplemental program, increased rebates and increased state revenues. These gains are either one time gains or may be reversed as state income decreases due to economic pressure from the fiscal crisis. Indeed these gains alone will not be enough to keep up with the pressures of a growing epidemic. ADAP’s client base continued to grow last year gaining at least 8000 new clients. The number of prescriptions per client continues to increase as does the cost of drug expenditures. More troubling, it is likely that State income will decline due to the anticipated recession, placing pressure on State budgets as well.

A particular issue which the majority of experts identified is that as ADAP has stabilized, it has become more difficult for patients to access treatment and care services including primary care. There is now a concern that waiting lists are developing for patients to see qualified physicians and other healthcare providers. At the same time there has also been a decline in the supportive services that help patients to enter and maintain their medical regimens, including non-medical case management, transportation, stable housing, access to food and to nutrition services, and access to translators. Additionally experts state that there needs to be even more focus on issues related alcohol and other drugs and mental health disorders.

This interdependence of programs speaks to the variety of needs of people living with HIV. Congress and the new administration must ensure that the benefits of ADAP are not lost as the U.S. enters a period of health care reform. In fact health care reform proposals should seek to improve ADAP, offering greater access to more medications for as many people as possible.

Additionally, hundreds of HIV/AIDS organizations across the country are calling on the next president of the United States to create a National AIDS Strategy to improve treatment outcomes for people living with HIV using evidence-based programming. The ability of ADAP to provide medications for so many people at relatively low cost should be improved. At the same time, ADAP should be strengthened by helping to provide credible service targets and annual reporting on progress towards goals. Additionally a National AIDS Strategy would seek to identify clear priorities for action across federal agencies and assign responsibilities and timelines for follow-through. It should include as a primary focus all groups at elevated risk, with particular attention to African American women and men, and gay men of all races, who are experiencing the brunt of the U.S. epidemic.

ADAP, as a successful program for people living with HIV/AIDS must continue to be available to the clients who need it. A particular strength for ADAP is that its purpose is relatively limited and it is an uncontested need. The provision of drugs can be easily measured and states and managers are already accountable for ensuring strong results.

While it is certainly true that ensuring that drug prices are set as low as possible and ensuring distribution to populations is important, state ADAPs and groups such as the ADAP Crisis Task Force appear to handle these issues quite well. The main issues for ADAP are less related to structural reform and much more to the need to ensure access to the program. The greatest needs are access to primary care services, removing barriers from treatment and care, ensuring access to needed support services and the need to provide outreach to people living with HIV who are not in care either because they don't know that they have HIV or are experiencing a barrier to care of some support.

The AIDS Drug Assistance Program has successfully negotiated the needs of people living with HIV for more than 20 years. At the same time the ability of ADAP to provide access to essential medications remains dependent on not only discretionary funding from the federal government but also a host of factors ranging from State contributions, underlying Medicaid programs, drug company rebates and more. People living with HIV who are dependent on drugs from ADAP thus are also interdependent with numerous other programs at the federal, State and local levels.

ADAP continues in its paramount role as *the* safety net program for people living with HIV who need drugs in the U.S. Therefore as the United States reviews health care, either through a health

care reform process in Congress or as part of a National AIDS Strategy in the new administration, it must carefully consider how to ensure continuity, improvement and expansion of ADAP.

## APPENDIX A

### *List of Policy Options*

- *Policy Option 1: The President should propose and the House and Senate Appropriators must increase funding for ADAP at the level of Need.*
- *Policy Option 2: Review State contributions and work with state activists to encourage individual states that make little or no contribution to begin doing so.*
- *Policy Option 3: Review current state match requirements and suggest legislative changes that require states to match at some level federal ADAP spending with state spending.*
- *Policy Option 4: States should be encouraged to use the insurance option where possible. Congress should review mechanisms to expand full insurance coverage for people who are eligible for ADAP.*
- *Policy Option 5: In accordance with current federal statute, (Veteran’s Health Care Act), maintain the current price negotiation methods with individual pharmaceutical companies described above.*
- *Policy Option 6: Allow all State ADAPs to have access to funding negotiated by the Department of Defense as is currently allowed by Washington D.C. if it is lower than the negotiated price.*
- *Policy Option 7: Change the Medicare law or the interpretation of the current law so that ADAP expenditures will count as TrOOP.*
- *Policy Option 8: Encourage States to ensure that their State ADAPs pay for beneficiary costs in the “donut hole” along with other Medicare wrap-around costs.*
- *Policy Option 9: Encourage states to investigate if the creation of SPAPs for HIV/AIDS beneficiaries is feasible and would result in cost savings to ADAP in their state. HRSA and CMS can provide technical assistance in the creation of SPAPs.*
- *Policy Option 10: Congress should pass the Early Treatment for HIV Act (ETHA) while ensuring access to social support services continue and that States have enough incentive to implement it. Advocates for the change must then work at the state level to ensure that states alter their Medicaid programs to allow income-eligible person living with HIV to enroll.*
- *Policy Option 11: Transform the ADAP Program, along with other Ryan White services, into an entitlement program for people living with HIV/AIDS*
- *Policy Option 12: Increase flexibility to allow ADAPs to spend funds on adherence services and outreach to individuals who are not currently accessing care.*
- *Policy Option 13: Increase the flexibility and availability of Minority AIDS Initiative funds to allow greater spending on ADAP. Such funds are the only ADAP funds used for outreach.*
- *Policy Option 14: Congress must ensure that funding for all Parts of the CARE Act beyond ADAP and other healthcare programs meets the full need of providing treatment and care including ensuring that all people who know that they are HIV-positive are able to receive high quality treatment and care including supportive services.*
- *Policy Option 15: Alleviate state variation by requiring states to set a floor for eligibility of 350% of the federal poverty level*
- *Policy Option 16: Require a stronger formulary that includes all antiretrovirals and drugs for opportunistic infections.*
- *Policy Option 17: Create greater portability by ensuring that beneficiaries receive comparable medications, services and programming in each State.*

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- *Policy Option 24: Change the funding amount that may remain unobligated from 2% to 5% and relax one or both of the penalties for not complying with the unobligated funding requirement.*
- *Policy Option 25: HRSA should review and change requirements so that rebate income is not considered to be program income and may therefore accrue after a grant year has ended. If HRSA fails to act, Congress should clearly state that ADAP funds are exempt from policies requiring ADAP rebate dollars to be expended before federal funds.*

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