White Paper – The History and Status of the ADAP Funding Crisis – as of August 2003

The Current ADAP Crisis status as of Month #5 of the FY '03 Funded Program Year (August 2003)

The growth in ADAP need is fueled by the success of HAART in extending the lives of people living with HIV/AIDS and compounded by HIV+ patients losing public health insurance access (e.g. Medicaid) and/or private health insurance coverage (e.g. losing jobs and hitting private policy caps.) plus successful testing and outreach efforts, additions of drugs to complicated HAART regimens, significant new HIV infections each year and a certain amount of "medical cost inflation". With reasonable resource stability and well recognized US AIDS epidemic trends the ADAP program can be expected to generate an increased need of $100 to $200 Million each year. If resources are not increased by that amount each year "structural deficits" begin to show up in the programs at the State level which are dealt with by creating "waiting lists", capping program expenditures, removing drugs from ADAP formularies, reducing eligibility and the like. The historical national monthly increase of about 600 additional surviving and utilizing HIV+ ADAP clients has been reasonably steady for some years now. Patients thus continue to look to ADAP when other access routes to HIV care and treatment are closed to them. When patients do try to enroll they either are provided access to care through ADAP – or NOT.

ADAP was generally well funded from FY '96 through FY '00 with active and open bi-partisan Congressional support. ADAP related crises did occur but tended to be a function of new programs, rapid scale up, State level resource needs, or local health care delivery issues. Underfunding on a serious nationwide federal level started in FY '01 and continues.

We deal with some aspects of this progression below with the emphasis based on our annual ADAP program data collections as part of the Kaiser Family Foundation supported annual "ADAP Monitoring Report" carried out by our members, NASTAD (National Alliance of State and Territorial AIDS Directors) and ATDN (AIDS Treatment Data Network). We use early data from this process to generate our yearly "need" forecast which we express in terms of an assessment of the year we are in plus the year which must be covered in the next ADAP appropriations cycle.

Projection Methods

The ADAP Working Group's data committee utilizes a computer model developed by respected pharmacoeconomists (Mauskopf JA, Tolson JM, Simpson KN, Pham SV, Albright J. The Impact of Zidovudine-Based Triple Combination Therapy on an AIDS Drug Assistance Program. JAIDS 2000;23(4) Apr 1: 302-313). The model uses real world information about the immune system status of ADAP clients to project the need for preventive and acute treatment with outpatient drugs. Actual ADAP monthly utilization data collected by the ADAP Monitoring Project provides the basic growth trend for the model. The cost of providing the standard of care to these utilizing ADAP clients on a month-by-month basis are projected out to March 31, 2005.

Base Case Assumptions

Starting with a base ADAP population from June 02, a monthly average growth is applied to the model. Utilization patterns for antiretrovirals and OI Prophylaxis are provided by Pennsylvania and Florida ADAPs. The cost of ARVs are based on an average of actual prices paid by ADAPs, including discounts mandated by the 340 B program, inflation rate adjusted. In keeping with the current standard of care for the treatment of HIV disease, the cost of management of treatment side-effects **is** also included.

ADAP Cost Containment

Increasing number of ADAP clients are being maintained on their existing health insurance through the use of ADAP funds. This is a much more cost-effective use of ADAP dollars. In FY 2002, the average cost of insurance premiums for an ADAP client is $3,546 per year.

- **Health Insurance Continuation Plans:** Results from FY2000 to FY2002 are used to project the enrollment and total cost of the insurance programs for 2003.

Program structural deficits

Individuals who are eligible for ADAP, but were not served by the program due to funding shortfalls, are expected to enter into the program at the start of a new fiscal year. The number of people waiting to access treatment through ADAP is dependent on the size of the shortfall each year.

- **Waiting Lists:** Assumes that 1200 patients will be on waitlists in 2003.

The Forecast Period: Is from today's date through the end of the FY '04 Funded ADAP Program Year, March 31st, 2005. A total of 22 Months of HIV/AIDS treatment access.

FY 2003 (April 2003 – March 2004) and FY 2004 (April 2004 – March 2005)

- Starting population (June 02) = 84,378
- Monthly growth = 635 (low = 600, high = 670)
- CD4 distribution = national ADAP totals (<50, 9.0%; 50-99, 9.0%; 100-149, 9.0%; 150-199, 9.0%; 200-299, 13.6%; 300+, 50.2%)
- Adherence rate = 95%
- Prophylaxis only = 10% (background rate for those on therapy is based on FL: Of the remaining 90%: 3% mono, 5% dual, 73% triple, 15% quad, 4% quint and higher; average ARVs per regimen = 3.12)
- Antiretroviral use based on PA ADAP (June 2001)
- ARV cost = AWP (October 01, 2002) – 23.9%
- Inflation rate for OIs, and other drugs = 4.6% per year (CPI for medical care)
- Inflation rate for ART = 1.3% per year (CPI for all items)
- Other costs (PMPM): Hyperlipidemia $5.48, insulin resistance $2.77, cardiovascular $5.32, gastrointestinal $11.58, and anti-diarrheals $1.44 (total: $26.60 PMPM)

Assumptions Based on New Developments in Treatment

- **New Therapies for Treatment-Experienced Patients:** Market share data was used to estimate the expected need for a new class of antiretrovirals, entry inhibitors (EIs). This estimate exceeded the production capacity reported by the manufacturer. Due to this expected drug shortage, T-20, the first drug approved in this class, utilization is based on the available supply as production ramps up to reach 15,000 available slots globally by the end of 2003. Assuming ADAP covers 20% of the people currently in treatment, the available T-20 slots will be 2,496 by the end of FY03 and 4,536 by the end of FY 04. The AWP of T-20 is assumed to be $25,463/year. T-20 is scheduled to launch at the end of first quarter of 2003 (calendar year). Since the NAWG FY 2003 begins April 1, 2003 on the calendar year, it is assumed that access to T-20 begins at the start of FY 2003.

- Due to the recent introduction of more effective treatments for hepatitis C, future utilization of hepatitis C treatment is more difficult to estimate. For the current estimate it is assumed that 38% of all patients are coinfected with HIV and Hepatitis C based on reported estimates ranging from 25% (Thomas 2002) to more than 40% (Taylor et al, IDSA 2002); however, up to 90% who were infected with HIV from IDU are HCV-coinfected (ref CDC Hepatitis C Virus and HIV Coinfection 2002). Overall, only 4% of those coinfected are treated. This figure is based on data presented from the Veterans Health Administration. The cost of pegylated interferon combined with ribavirin is estimated to be $24,500 per year for a completed course based on AWP less 23.9% discount. It is assuming that 50% of patients discontinue treatment after three months due to lack of efficacy. For 2003, an adjustment is made for uptake of a new product.

History of ADAP Program Restrictions due to Federal funding shortfall:

At the end of FY 2001 - $ 57 Million Federal funding shortfall

Ten ADAPs reported program restrictions as of February 2002:

Alabama: capped enrollment (300 on waiting list)
Georgia: capped enrollment (700 on waiting list)
Guam: capped enrollment
Idaho: capped enrollment
Kentucky: capped enrollment
Maine: (ARV restrictions)
North Carolina: capped enrollment
South Dakota: capped enrollment (22 on waiting list)
Texas: (ARV restrictions)
Wyoming: capped enrollment

At the end of FY 2002 – $82 Million Federal funding shortfall

13 ADAPs reported program restrictions as of March 2003, including 4 ADAPs lowering financial eligibility criteria.

Alabama: capped enrollment (104 on waiting list)
Guam: capped enrollment (4 on waiting list)
Idaho: capped enrollment (no waiting list) and monthly expenditure cap
Kentucky: capped enrollment (116 on waiting list)
Nebraska: capped enrollment (24 on waiting list) and reduced formulary
New York: reduced formulary; mandatory generics; prescription limits
Oregon: capped enrollment; reduced formulary; lowered financial eligibility (145 on waiting list)
South Dakota: capped enrollment and annual expenditure cap (49 on waiting list)
Texas: restricted access to antiretroviral medication (ARV)
U.S. Virgin Islands: lowered financial eligibility
Washington: lowered financial eligibility criteria; reduced formulary; imposed cost-sharing
West Virginia: capped enrollment (4 on waiting list)
Wyoming: capped enrollment (3 on waiting list); lowered financial eligibility; reduced formulary; 90-day waiting period

As of August 2003/ Mid FY 2003 - $145 Million Federal funding shortfall –

17 ADAPs reported program restrictions as of August 2003.

Alabama: capped enrollment (89 on waiting list)
Alaska: capped enrollment (1 on waiting list)
Arkansas: capped enrollment
Colorado: capped enrollment, reduced formulary (80 on waiting list)
Idaho: capped enrollment, monthly expenditure cap
Indiana: capped enrollment (48 on waiting list)
Kentucky: capped enrollment (165 on waiting list)
Montana: capped enrollment (4 on waiting list)
Nebraska: capped enrollment, reduced formulary (30 on waiting list)
New York: reduced formulary, mandatory generics, prescription limits
North Carolina: capped enrollment
Oklahoma: reduced formulary and annual expenditure cap
Oregon: capped enrollment, reduced formulary, lowered financial eligibility (228 on waiting list)
South Dakota: capped enrollment (50 on waiting list)
U.S. Virgin Islands: lowered financial eligibility
Washington: lowered financial eligibility criteria, reduced formulary, imposed cost-sharing
West Virginia: capped enrollment (14 on waiting list)

N.B.

- **Of the FY '04 $283 Million total need the following component allowances for FY 2004 are of interest:**
  - **Waiting List $14.8 million**
  - **Insurance $22.9 million**
  - **Co-Infection HCV $28.5 million**
  - **New Classes of ARV $69.8 million**

- **In our projections treatment costs for HIV+ ADAP Patients are projected at the following levels:**
  - **$1,114.00 @ Month and $13,368.00 @ year**
- **Waiting List: Assumes that 1200 patients will be on waitlists in 2003.**
  - **We are more than half way there at month #5 with 709.**
- **Health Insurance Continuation Plans:**
  - **Results from FY2000 to FY2002 are used to project the enrollment and total cost of the insurance programs for calendar 2003 & FY 2004.**

Extensive additional Materials are available from The ADAP Working Group and our members upon request.

History & Data – At A Glance

Program Restrictions	**February-02**	**February-03**	**August-03**		
States with Restrictions	10	13	17		
States with Capped Enrollment	7	9	13		
States with Reduced Financial Eligiblity		4	3		
States with Reduced Formulary or Access Limitations	6	8	6		
Total Number on Waiting Lists	1,022	449	709		
Clients & Expenditures	**Jun-98**	**Jun-99**	**Jun-00**	**Jun-01**	**Jun-02**
ADAP Monthly Clients Served	52,773	61,822	69,407	76,743	84,489
ADAP Monthly Expenditures	$36,636,193	$46,778,490	$58,465,169	$63,789,458	$70,705,142
Budget	**FY 98**	**FY 99**	**FY 00**	**FY 01**	**FY 02**
Reported Total Annual Budget *	$510,181,254	$665,530,408	$724,493,196	$810,202,138	$878,610,754
ADAP Earmark Funds	$285,500,000	$460,600,000	$527,600,000	$571,300,000	$619,830,000
State Funds	$119,400,000	$125,500,000	$128,800,000	$149,600,000	$160,385,979
Growing Deficit	**FY 01**	**FY 02**	**FY 03**	**FY 04**	
Projected Federal Shortfall	**$57,000,000**	**$82,000,000**	**$145,000,000**	**$283,000,000**	

Notes:
* National ADAP Monitoring Report

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Prepared by the Data Subcommittee of
The ADAP Working Group
1775 "T" Street NW
Washington, DC 20009

PH: (202) 588-1775
FX: (202) 588-8868

William E Arnold, Director
The ADAP Working Group