Congress of the United States
House of Representatives
Washington, D.C. 20515

June 17, 2004

The Honorable Tommy G. Thompson
Secretary of Health and Human Services
U.S. Department of Health and Human Services
200 Independence Avenue, SW
Washington, DC 20201

Dear Mr. Secretary:

On February 5, and again on May 4, we wrote to you about the urgent need for additional federal funding for the AIDS Drug Assistance Program (ADAP), which provides essential HIV/AIDS medications to Americans who lack adequate health insurance. We have yet to receive a response from you to these letters. We are writing again today to make you aware of your own agency's conclusion that significantly more funding is urgently needed.

In our prior letters, we expressed concern regarding the growing gap between public health needs and available funding. The Centers for Disease Control and Prevention (CDC) is promoting HIV testing in order to diagnose Americans who are currently unaware they are infected. This campaign is creating new demand for HIV treatments and medical care. For four months, we have warned that the President's fiscal year 2005 budget for HIV/AIDS care and treatment services falls far short of what is needed.

Our conclusion has now been echoed by experts in your own Department. On May 7, 2004, Administrator of the Health Resources and Services Administration (HRSA) Betty James Duke provided an estimate of the impact of the CDC initiative on the demand for HIV/AIDS services funded through the Ryan White CARE Act (attached). HRSA found:

- The CDC initiative will identify as many as 19,000 HIV-infected persons in 2004 and 2005;

- To care for these individuals in clinical settings funded by the Ryan White CARE Act, as many as 113 additional full-time clinicians and staff will need to be hired;

- For all payers, clinical expenses for these individuals could exceed $20 million, and drug expenses could exceed $95 million; and

- The direct cost to the Ryan White CARE Act programs will range from $26.6 to $52.2 million.

These projections, which are likely underestimates, are generally in line with our estimate on February 5 that an additional $45.3 million would be needed in the fiscal year 2005 budget to account for medication expenses associated with the CDC initiative.

We urge you to pay attention to HRSA's conclusion. In addition to accounting for expenses associated with the CDC initiative, the President's budget needs to address chronic underfunding of the program. According to the National Alliance of State and Territorial AIDS Directors, an additional $171.7 million is needed to address the continuing increases in the number of people in need of the program, to clear waiting lists, to remove medical restrictions, and to add newly approved drugs to the formulary.

At a time when HIV treatment is so effective, it is inexcusable that so many Americans do not have access to care. We ask again that you support adequate funding to address the growing crisis in HIV/AIDS services in the United States.

Sincerely,

Nancy Pelosi
Member of Congress

Steny H. Hoyer
Member of Congress

Henry A. Waxman
Member of Congress

Barney Frank
Member of Congress

Sherrod Brown
Member of Congress

Donna M. Christensen
Member of Congress

Barbara Lee
Member of Congress

Tammy Baldwin
Member of Congress

Enclosures (3)

cc: The Honorable Joshua Bolton, Director
Office of Management and Budget

The Honorable C.W. Bill Young, Chair
The Honorable David R. Obey, Ranking Minority Member
Committee on Appropriations

Advancing HIV Prevention: Opportunities for HRSA Participation and Estimates of Impact on CARE

Laura W. Cheever, M.D., ScM
Deputy Director, HIV/AIDS Bureau
Health Resources and Services Administration

AHP: HRSA Collaboration

- HRSA-wide workgroup to examine the impact across HRSA programs
- SPNS Prevention with Positives grantees
- Development of joint guidelines for integrated case management services
- Funding of perinatal hotline
- "3tc" meeting to focus on AHP
- Regional AETC projects

AHP: Estimating Impact on Care

- A "mosaic" of data and assumptions
- Payer Source of those entering care
  - RWCA Data Report 2002 (all pts receiving CARE Act services
  - Title III program data 2001

AHP: Payer Source of those entering care

Payer	Percent
No insurance	45
Medicaid	30
Other (state, VA, etc)	12
Private insurance	11
Medicare	2

AHP: Newly diagnosed patients entering care

- Number of patients entering care:
  - 65% newly diagnosed enter Year 1
  - 25% enter Year 2
  - 10% enter after Year 2
- Newly diagnosed entering in:
  - 2004: 3,800 - 7,500
  - 2005: 3,900 – 7,800

AHP: Estimating Impact on Care

- Additional Provider Burden
  - Title III data 2000, 2001
  - Total FTEs and clinical staff (MD, DO, RN, PA, NP)
  - Difficult to estimate absorptive capacity

Provider Burden

- If absorptive capacity at 80-90%, then no increase in FTEs
- If absorptive capacity at 100%, then:
  - 28-55 additional primary care FTEs 2004
    - 16-32 clinical staff
  - 29-55 additional primary care FTEs 2005
    - 17-33 clinical staff
  - FTE increase greatest in MidAtlantic, South, West

Outpatient medical costs

- Outpatient costs including laboratory testing (not medication)
- Data Sources
  - RWCA Data Report 2002 for # patient visits
  - HIV Research Network estimated based on HCSUS cost estimates adjusted for Medical care inflation rate of CPI

Outpatient medical costs

- Number of visits
  - Median 5.06, Average 6.95
- Average cost per visit: $214
- Additional cost (median # visits)
  - 2004: $4.11- $8.12 million
  - 2005: $4.22-$8.45 million
- Additional cost (average # visits)
  - 2004: $5.65- $11.15 million
  - 2005: $5.8-$11.6 million

Medication Costs

- Estimate 55% of newly diagnosed entering care will require medication
- Annual per patient cost of medication (based on ADAP program costs): $11,300
- Additional medication costs
  - 2004: $23.6-$46.9 million
  - 2005: $24.2-$48.5 million

AHP: Total estimated additional cost of care (in millions)

- FY 04*: $29.3 - 58.1
  - Ryan White CARE Act: $13.1 - 26.1
    - Medical care: $2.5 - 5.0
    - Medication: $10.6 - 21.1
- FY 05*: $30.0-60.1
  - Ryan White CARE Act: $13.5 – 27.1
    - Medical care: $2.6 - 5.2
    - Medication: $10.9 - 21.9

* All payer sources

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DEPARTMENT OF HEALTH & HUMAN SERVICES

Health Resources and Services Administration

Rockville, Maryland 20857

MAY 7 2004

TO: CDC/HRSA Advisory Committee on HIV and STD Prevention and Treatment

FROM: Administrator

SUBJECT: CDC/HRSA Advisory Committee on HIV and STD Prevention and Treatment Information Request

This is in response to the CDC/HRSA Advisory Committee on HIV and STD Prevention and Treatment request for a report from the Centers for Disease Control and Prevention (CDC) and the Health Resources and Services Administration (HRSA) on the cost implications of the new CDC Advancing HIV Prevention Initiative on the demand for Ryan White Comprehensive AIDS Resources Emergency (CARE) Act services. Attached is the response prepared by HRSA. The data included reflects an increased need for care and treatment services due to the implementation of the Initiative.

We will keep you apprised of our progress in responding to this important initiative and its' impact on the Ryan White CARE Act and other HRSA HIV-related programs.

Betty James Duke

Attachment

Report to the CDC/HRSA Advisory Committee on HIV and STD Prevention and Treatment

HIV-infected persons newly identified as a result of the Centers for Disease Control and Prevention (CDC) Advancing HIV Prevention (AHP) Initiative activities will concurrently increase the demand for HIV care and treatment. The additional resources needed to provide care and treatment for these newly diagnosed persons are estimated based on the estimated number of HIV-infected persons that will be identified through AHP. In addition, the potential insurance status of these newly identified persons living with HIV is estimated to provide insight into the impact of the increased demand for care on the health care delivery system.

The demographic characteristics of newly identified HIV-infected persons as estimated by CDC are very similar to the characteristics of HIV-positive clients receiving outpatient care from Ryan White Comprehensive AIDS Resources Emergency (CARE) Act providers. CARE Act providers are generally required to report on all clients who received services eligible for CARE Act Titles I, II, III, or IV funding, regardless of the actual funding source used to pay for those services. Thus, insurance status as reported by CARE Act providers includes the full spectrum of payer sources found in the U.S. health care system. As the newly diagnosed first enter care, we estimate that 45 percent will have no insurance and 30 percent will be Medicaid recipients. Eleven percent of the newly identified HIV-infected persons will have private insurance and 2 percent will be Medicare enrollees. An additional 12 percent will have other types of insurance.

Increased resource needs have been estimated in terms of the number of Full Time Equivalents (FTEs) required to provide care, the cost of outpatient medical care (including laboratory costs but not medications), and the cost of medications. We estimated that 3,800 - 7,500 of the 5,800 - 11,500 HIV-infected persons newly identified in 2004 will enter care in that year. Based on patient-to-staff ratios in Ryan White CARE Act clinical settings, an estimated 28 to 55 additional primary care staff FTEs will be needed to care for persons newly identified through AHP and entering care in 2004. This includes both clinical and ancillary staff FTEs. Among these staff, 16 to 32 FTEs will be clinical staff providing direct patient care (MD, DO, PA, NP, RN, etc.). We further estimate that an additional 29 to 58 primary care staff FTEs (including 17 – 33 clinical staff FTEs) will be needed to care for the estimated 3,900 – 7,800 newly identified HIV-infected persons entering care in 2005. The greatest need for additional FTEs is anticipated in the Mid Atlantic, South, and West.

The costs of providing outpatient medical care (including laboratory tests but not medications) are estimated based on the national estimate of HIV care cost derived from the HIV Cost and Service Utilization Study adjusted for the U.S. medical inflation rate of the Consumer Price Index. A cost of $214 per visit is used to calculate resources needed to provide outpatient care. Based on a **median** of 5.06 visits per patient per year as derived from 2002 CARE Act program data, we estimate an additional cost of approximately $4.11 - $8.12 million to provide outpatient care to persons newly diagnosed through AHP in 2004. In 2005, estimated additional care costs are $4.22 - $8.45 million. In 2002, the **average** number of visits per patient per year in CARE Act clinical settings was 6.95 visits per patient

per year. An alternate estimate using the average number of visits per patient per year results in estimated care costs of $5.65 - $11.15 million in 2004 and $5.8 - $11.6 million in 2005.

It is estimated that 55 percent of the newly diagnosed HIV-infected persons entering care will require medications to treat their HIV disease. Using an estimated annual per person cost of $11,300 for medications to treat HIV disease, we estimate additional medication costs of $23.6 - $46.9 million in 2004 and $24.2 - $48.5 million in 2005.

Report to the CDC/HRSA Advisory Committee on HIV and STD Prevention and Treatment

The goal of CDC's new initiative, "*Advancing HIV Prevention: New Strategies for a Changing Epidemic*" is to reduce barriers to early diagnosis of HIV infection and increase access to quality medical care and ongoing prevention services for persons living with HIV and their partners. CDC estimates that there are between 180,000 and 280,000 persons living with HIV who do not yet know they are infected. Annually, about 60,000 persons are diagnosed with HIV in the U.S., of whom 18,000 are diagnosed in publicly-funded HIV counseling and testing sites. In November 2003, the CDC/HRSA Advisory Committee on HIV and STD Prevention and Treatment requested CDC and HRSA to estimate the number of persons who will be newly identified as a result of Advancing HIV Prevention (AHP) strategies and programs and the resulting increased demand for HIV care and treatment that would be associated with those diagnoses.

Implementation of these strategies through CDC funded programs and activities will increase the numbers of HIV tests performed by 300,000 -600,000 in 2004 and by 150,000 -300,000 in 2005. We estimate that this testing will increase the numbers of persons identified with HIV by 5,800-11,500 persons in 2004 and by 3,800- 7,600 persons in 2005. We anticipate that these persons will be located mostly in the South and Northeast, followed by the West and Midwest. We estimate that approximately 75% of the newly identified HIV infected persons will be members of minority communities, 70% will be male, 40% men who have sex with men, 20% injection drug users and 40% persons infected through heterosexual transmission.

All persons newly diagnosed with HIV should be referred to assess necessary medical, prevention and social service needs. Depending on their CD4 count, some persons will need treatment for HIV and prophylaxis to prevent opportunistic infections. Current

HHS guidelines recommend treatment be considered for persons with ≤350 CD4 T-cells/mm^3. Using these guidelines, about 55% of newly identified persons (approximately 3,000-6,500 persons in 2004) will be eligible for treatment at diagnosis or within the first year after diagnosis.

This estimate is based upon increases in HIV testing and improved targeting of testing to person at high risk of being infected with HIV by programs and activities supported by CDC funding. Recommendations and strategies of AHP are being implemented by other government agencies and by partners in the medical and prevention communities which will also increase the number of persons tested and newly identified with HIV and who will need care and services. However, we cannot estimate the effect of these efforts at this time and are working with our partners to obtain this information in the future.

As AHP is fully implemented, more persons will be identified earlier in their HIV infection. If they are provided appropriate care and prevention services to prevent transmission to partners, the number of newly acquired infections will decrease, helping CDC to achieve its overall goal to reduce HIV incidence in the United States.

Information on the insurance status of new identified persons living with HIV and the resources needed for their care and treatment under the Ryan-White CARE Act program will be provided by HRSA.