

August 13, 1996



Health Division



Office of Management and Budget
Executive Office of the President
Washington, DC 20503

Please route to:

Richard Turman
Barry Clendenin
Beth Rossman

Decision needed _____
Please sign _____
Per your request X
Please comment _____
For your information _____

Subject: **L/HHS Letter Update for AIDS
Drug Amendment**

With informational copies for
HPS and HD Chrons, NEM

Phone: 202/395-7791
Fax: 202/395-3910
Room: #7026

From: Greg White ^{GW}

Per your request, we have updated below the Ryan White portion of the letter for the FY 1997 L/HHS bill to account for the \$65 million Budget Amendment for AIDS Drug Assistance Program (ADAP) activities. Attached also is an e-mail that summarizes current FY 1997 funding for Ryan White (Tab A) and a copy of the previous Ryan White text in the letter for House action which the text below would replace (Tab B).

Please let us know if you have any questions.

Protecting Health

The House-passed bill would provide \$812 million for Ryan White AIDS Treatment Grants, \$83 million below the comparable request, adjusted for the Ryan White CARE Act amendments of 1996. Since the House completed action on the bill, the Administration has increased its request by \$65 million to \$117 million for specific funding for State AIDS Drug Assistance Program (ADAP) activities authorized in Title II. While the Administration is encouraged that the House recommended \$75 million for this ADAP set-aside, an increase of \$23 million above FY 1996, the Administration urges the Committee to fund the full request of \$117 million. The Administration is also concerned that the House funded the other activities authorized in Title II \$18 million below the President's request. The Administration urges the Committee to fund these activities at the requested level of \$233 million.

In addition, the Administration is concerned that funding provided below the request in the House bill is insufficient to keep up with increasing case loads in the 49 cities currently receiving Title I assistance and the 150 local clinics that provide Title III(b) early intervention services to those with, or at-risk of developing HIV.

TAB A

EXECUTIVE OFFICE OF THE PRESIDENT

08-Aug-1996 02:54pm

TO: Nancy-Ann E. Min
 TO: Sarah A. Bianchi

FROM: William G. White
 Office of Mgmt and Budget, HD

CC: Barry T. Clendenin
 CC: Richard J. Turman
 CC: Jim R. Esquea

SUBJECT: Update on FY97 Ryan White Funding

Now that the President has signed the \$65 million ADAP Budget Amendment, we prepared the following table which summarizes how the Administration's FY97 request for Ryan White compares with FY97 House action. [Note that we have broken down the Title II line into 2 different funding streams: (1) the Regular Title II grant which funds consortia, ADAP, insurance continuation and home and community-based services; and (2) the ADAP set-aside which funds strictly ADAP activities.]

You will note that the House provided increases for most Titles of Ryan White over FY96, but not to the same level requested by the President.

Ryan White Funding FY96-97
 (BA -- \$ in Millions)

	FY96 Enacted	FY97 Budget	FY97 House	House +/- Budget
Title I (Cities)	392	424	402	-22
Title II (States)				
Reg. Grant	209	233	216	-17
ADAP Set-Aside	52	117*	75	-42
Total Title II	261	350*	291	-59
Title IIIb (Clinics)	57	65	62	-3
Title IV (Pediatric AIDS)	29	34	34	0
Title V (Dental)	7	7	8	+1
Title VI (AIDS ETCS)	12	16	16	0
TOTAL RYAN WHITE	757	896	812	-84

*Includes the \$65 million ADAP Budget Amendment.

TAB B

inappropriately restrict the ability of enforcement agencies to safeguard child safety, and enforce the National Labor Relations Act. The Administration is also concerned that the House-passed bill does not fund the National Institute for Occupational Safety and Health or the former Bureau of Mines activities transferred to the Centers for Disease Control at the requested level.

The Administration opposes the 40-percent cut below the FY 1996 level for the Bureau of International Labor Affairs. The funding level provided by the House would constrain the Bureau's ability to work on child labor and workers' rights issues.

The Administration commends the House for removing the prohibition on the Occupational Safety and Health Administration's (OSHA's) ability to develop or issue any proposed or final standards or guidelines on the subject of ergonomic protection. The Senate is urged to concur with the House and to allow the Department of Labor to address the most rapidly growing workplace health problem.

Protecting Health

The House-passed bill would provide \$812 million for Ryan White AIDS Treatment Grants, \$18 million below the comparable FY 1997 request, adjusted for the Ryan White CARE Act amendments of 1996. While the Administration is encouraged that the House has increased funding above the President's request specifically for Title II State AIDS Drug Assistance Program activities, we are concerned that other activities in Title II receive \$17 million less than the level requested by the President. The Administration is also concerned that funding provided below the request for some other Titles in the Ryan White CARE Act is insufficient to keep up with increasing case loads in the 49 cities currently receiving Title I assistance and the 150 local clinics that provide Title III(b) early intervention services to those with, or at-risk of developing HIV.

The Administration is also concerned that the House-passed bill does not appropriate a specific amount for AIDS research through a single appropriation for the National Institutes of Health's (NIH's) Office of AIDS Research as requested in the President's budget. The single appropriation helps NIH target NIH AIDS research funds effectively, minimizing duplication and inefficiencies across the 21 institutes and centers that carry out HIV/AIDS research.

Replaced by New

4

Insert on 8/13 Part 81.2.

NATIONAL ALLIANCE OF STATE AND TERRITORIAL AIDS DIRECTORS*"Ryan White"*

May 23, 1997

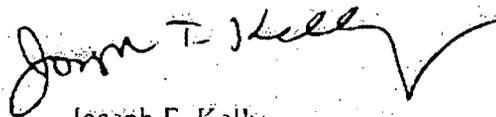
Dear Colleague:

I wanted to bring to your attention the attached letter from 12 of our nation's governors expressing their support for federal funding for Ryan White CARE Act Title II AIDS Drug Assistance Programs. These governors represent states which have reported 63% of the U.S. AIDS cases. Their support comes at a critical time as Congress and the Administration consider responses to the emergency in funding for access to breakthrough new AIDS therapies.

People with HIV disease who lack Medicaid coverage or access to private health insurance are forced – in rapidly increasing numbers – to depend on ADAPs in order to access revolutionary new HIV/AIDS therapies. Nationally, state ADAPs have reported a 77% increase in clients since January 1996. The programs are collectively averaging approximately 1,000 additional utilizing clients each month nationwide. The costs are growing too – states report a 37% increase in expenditures nationally during the last half of 1996. In 11 states (Arkansas, Connecticut, Idaho, Kentucky, Maryland, Mississippi, New Jersey, North Dakota, Texas, Utah, West Virginia) – the costs doubled or tripled in six months – forcing immediate and serious restrictions on accessibility to prevent total program collapse in several states.

The NIH and the Public Health Service are poised to release new clinical practice guidelines for treating HIV infection. The recommended goal of treatment will be to bring an individual's level of HIV infection down to undetectable levels to ward off further deterioration of the immune system. Although cost estimates of implementing these new guidelines have not been established by the Administration, these guidelines will have a critical effect on state ADAPs which will realize continuing client growth and overwhelming expenditures.

Sincerely,


Joseph F. Kelly
Deputy Director

Attachment

NACTAD**OFFICERS***Chair*Douglas H. Morgan
New Jersey
(609)864-5074*Vice Chair*Liza Solomon
Maryland
(410)747-5013*Chair-Elect*Randall Pope
Michigan
(517)335-8468*Secretary/Treasurer*Evelyn Blankenship Poust
North Carolina
(919)733-7301**EXECUTIVE COMMITTEE***Ex Officio*Wayne Sauseda
CaliforniaTerje Anderson
VermontJohn Abernethy
MassachusettsChase Bliss
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WashingtonJill DeBoer
MinnesotaTerrence Foley
WyomingChester Kelly
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PennsylvaniaGlenn Maki
New YorkRobert McAllister
OregonBeth Meyerson
MissouriArlene Rose
ArkansasCraig W. Thompson
MississippiBeth Weinstein
Connecticut**EXECUTIVE DIRECTOR**

Julie M. Scofield

May 21, 1997

The Honorable Arlen Specter
Chairman
Appropriations Subcommittee on Labor, HHS, Education
United States Senate
184 Dirksen Senate Office Building
Washington, DC 20510

Dear Chairman Specter:

As the chief elected official in our respective states, we would like to thank you for your efforts during the FY 1996 and 1997 appropriations cycles in supporting state AIDS Drug Assistance Programs (ADAPs). These funds are appropriated as a dedicated needs-based allocation within Title II of the Ryan White CARE Act specifically for expansion of state ADAPs to include new promising HIV treatments such as protease inhibitors.

Additionally, we would like to thank you for commensurate increases in state Title II non-dedicated core funding. These funds allow states the flexibility to provide other AIDS services such as viral load tests and insurance continuation as well as support for suburban and rural AIDS services.

Currently, the data are proving that state ADAPs save lives and money.

According to the Centers for Disease Control and Prevention, the estimated number of AIDS deaths declined by 13 percent during the first six months of 1996 as compared to the same period the previous year. This decline was attributed in most part to the introduction of new therapies and the corresponding state and federal funding to make these medicines available. In fact, some areas of the country, including metropolitan New York experienced as much as a 50 percent drop in AIDS death rates due in large part to new therapies and state efforts to make them available.

Furthermore, due to the efficiency of state ADAPs and the efficacy of new therapies, states are now grappling with the question of how to accommodate AIDS patients who want to leave the disability and Medicaid rolls and return to gainful employment. This is a positive result.

However, with all these optimistic developments, new AIDS therapies are expensive and state governments continue to need a partnership with the federal government to increase availability of new combination therapies. Therefore, we strongly urge you to continue your support for Title II CARE Act programs.

Again, thank you for all of your hard work on this issue.

The Honorable Arlen Specter

Page 2

Sincerely,

Gov. George E. Pataki

Gov. George E. Pataki, New York

Gov. Lawton Chiles

Gov. Lawton Chiles, Florida

Gov. Christine T. Whitman

Gov. Christine T. Whitman, New Jersey

Gov. Mel Carnahan

Gov. Mel Carnahan, Missouri

Gov. Pete Wilson

Gov. Pete Wilson, California

Gov. Robert J. Miller

Gov. Robert J. Miller, Nevada

Gov. Parris N. Glendening

Gov. Parris N. Glendening, Maryland

Gov. John Engler

Gov. John Engler, Michigan

Gov. Pedro Rossello

Gov. Pedro Rossello, Puerto Rico

Gov. John G. Rowland

Gov. John G. Rowland, Connecticut

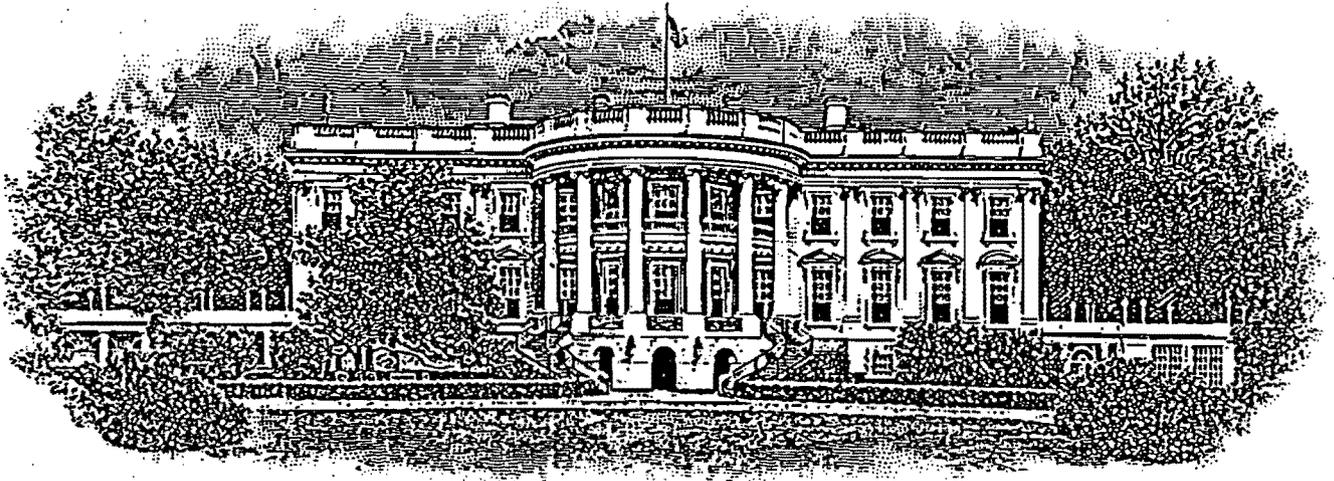
Gov. Gary Locke

Gov. Gary Locke, Washington

Gov. Arne H. Carlson

Gov. Arne H. Carlson, Minnesota

The White House



DOMESTIC POLICY

FACSIMILE TRANSMISSION COVER SHEET

TO: Laura Emmett

FAX NUMBER: 6-2878

TELEPHONE NUMBER: _____

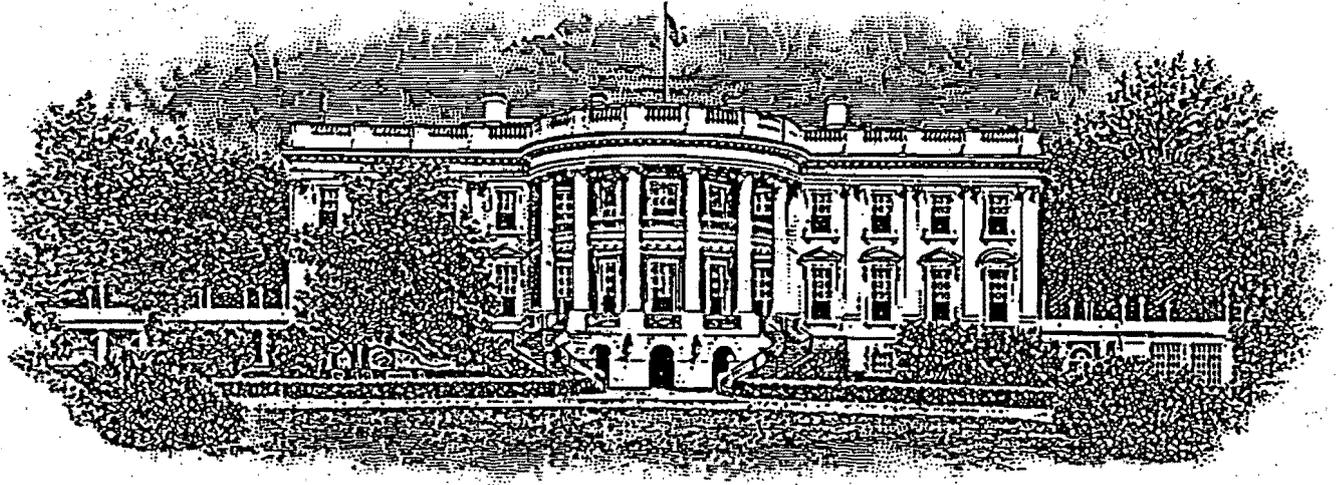
FROM: Sarah Bianchi

TELEPHONE NUMBER: _____

PAGES (INCLUDING COVER): _____

COMMENTS: _____

The White House



DOMESTIC POLICY

FACSIMILE TRANSMISSION COVER SHEET

TO: Ann Walker

FAX NUMBER: 6 2239

TELEPHONE NUMBER: _____

FROM: Sarah Biacere

TELEPHONE NUMBER: _____

PAGES (INCLUDING COVER): _____

COMMENTS: _____

Q: YESTERDAY THE HOUSE SAID THEY WERE GOING TO INCREASE AIDS DRUGS ASSISTANCE PROGRAMS (ADAP) BY \$132 MILLION AND INCREASE RYAN WHITE ANOTHER \$40 MILLION OVER THAT*. DOES THE PRESIDENT INTEND TO SUPPORT THIS INCREASE?

A: The President recognizes the important role these programs play in helping provide much needed treatment for people with HIV/AIDS. He has supported substantial increases for both ADAP and Ryan White as well as taken steps to ensure that the Medicaid program covers new drug treatments for people with HIV/AIDS.

A couple weeks ago, the Administration released guidelines on AIDS treatments. The release of the guidelines raised some important questions about the adequacy of current funding for programs like ADAP which help provide treatment to those who would not otherwise have access. The Department of Health and Human Services will make a recommendation on this shortly.

The President's leadership has been a major factor in giving people access to treatments that have helped bring down the number of people with AIDS by 19 percent in the first part of 1996. The President is proud that the CDC reports that this decrease can be attributed to our efforts to give greater access to medical care and improved drug treatments for people with HIV/AIDS.

The President is also well aware that our work is not done. Today, there are still between 650,000 and 900,000 Americans living with HIV, and we must continue our efforts to ensure these citizens have access to needed treatments.

* ADAP is funded under Ryan White. The total House increase in Ryan White is \$172 million above the President's budget. (\$132 for ADAP and \$40 million for other Ryan White Programs).

ACCESS TO TREATMENTS

(extension of MEDICAID...)

August 14, 1996



Health Division



Office of Management and Budget
Executive Office of the President
Washington, DC 20503

Please route to:

Beth Berman, fax 456-2239
Nancy-Ann Min

Decision needed _____
Please sign _____
Per your request x
Please comment _____
FYI _____

Through:

Barry Clendenin *BC*
Mark Miller *M*
Richard Turman *RT*

With Copies for: HD Chron, HFB Chron,
Meg

Phone: 202/395-7831
Fax: 202/395-3910
Room: #7026

Subject:

HCFA Fact Sheet on
Medicaid and AIDS

From:

BW
Bonnie Washington &
Greg White *GW*

Attached, per your request is a HCFA fact sheet on Medicaid coverage of people with AIDS. These estimates are outdated and will likely change in the next few months. The actuaries at HCFA are currently in the process of revising the estimates of Medicaid coverage and spending for AIDS in light of more recent data from CDC.

Please call Bonnie Washington at extension 5-7788 if you have any questions about this fact sheet.

Attachment



Department of Health and Human Services

FACT SHEET

June 1996

Medicaid Bureau

(410) 786-4577

MEDICAID AND ACQUIRED IMMUNE DEFICIENCY SYNDROME (AIDS) AND HUMAN IMMUNODEFICIENCY VIRUS (HIV) INFECTION

Serving at least 50 percent of all persons living with AIDS (PLWA) and up to 90 percent of all children with AIDS, Medicaid is the largest single payer of direct medical services for PLWAs. Estimated combined Federal and State Medicaid expenditures will be \$3.5 billion in fiscal year 1996, or about 25 percent of the aggregate cost of AIDS-related medical care.

- o States may provide optional services that are often appropriate for people with HIV/AIDS, such as targeted case management and hospice care. All States cover prescribed drugs, including various drugs for prophylactic treatment of AIDS-related opportunistic infections, FDA-approved drugs for treatment of primary HIV disease, such as reverse transcriptase inhibitors, FDA-approved protease inhibitors, and zidovudine (AZT). AZT can be provided to HIV-positive pregnant women and their infants to help prevent the transmission of HIV to those infants.
- o When cost-effective, States must pay the cost of premiums to continue employer-based health insurance policies of PLWAs eligible for Medicaid, or with low income and resources.
- o Fifteen States have elected to provide PLWAs cost-effective alternatives to confinement to a medical facility and expanded services through home and community-based services waiver programs, as optional services.
- o Most adults with AIDS or HIV-related illnesses who qualify for Medicaid do so because they are disabled, have low income, and limited assets. Individuals not considered disabled may qualify for Medicaid as a parent/caretaker relative or child receiving benefits under Aid to Families with Dependent Children (AFDC) or as a poverty-related pregnant woman or child.
- o HCFA works with the Public Health Service (PHS) to enhance collaboration between State Medicaid programs and grantees funded under the Ryan White Comprehensive AIDS Resources Emergency (CARE) Act of 1990.
- o HCFA monitors developments in national and State health care reform, such as managed care programs, to assess their impact on persons with HIV/AIDS.
- o States also work with HCFA and other Federal agencies to assure that persons with HIV infection and AIDS are not subject to discrimination in seeking access to Medicaid and Medicare services.
- o HCFA seeks to assure appropriate care for PLWAs through the development of national consumer information initiatives for HIV-positive pregnant women, and the issuance of letters to State Medicaid Agencies on priority AIDS issues (e.g., access to protease inhibitors and other prescription drugs, encouragement of HIV counseling and testing, etc.)

File VP
Medicaid / HIV

DRAFT

EXPANDING ELIGIBILITY FOR MEDICAID TO PERSONS WITH HIV DISEASE

More information about this project can be obtained by contacting
Christine Lubinski, AIDS Action Council of Washington, D.C. at (202) 986-1300, or
Robert Greenwald, AIDS Action Committee of Massachusetts, at (617) 450-1257.

DRAFT

EXPANDING ELIGIBILITY FOR MEDICAID TO PERSONS WITH HIV DISEASE

INTRODUCTION

Recent research has shown that a long-held assumption about AIDS was wrong—there is no initial dormant phase of HIV infection. Instead, the virus attacks the body's immune system from the outset. This improved understanding of how HIV functions, along with the advent of powerful new medications, has led to new recommendations for care and treatment. Specifically, experts now advise comprehensive care and treatment, often with combination drug therapy, from the earliest stages of HIV disease.

Despite the experts' recommendations for early treatment and the existence of effective drugs, significant obstacles to accessing care and medications remain for low income people living with HIV. Existing programs cannot meet the need for comprehensive health care and preventive services. The current Medicaid requirements force most HIV positive individuals to wait until they develop full-blown AIDS to become eligible for coverage, a model which is inconsistent with clinical standards, inhumane, and costly.

EARLY INTERVENTION WORKS, SAVING LIVES AND DOLLARS

The new standard of care for people with HIV emphasizes early clinical intervention, calling for both primary care and combination drug therapy, including protease inhibitors, at earlier stages of infection. The National Institutes of Health (NIH) report that "...it has been suggested that the best opportunity to eradicate HIV infection is provided by the initiation of potent combination antiretroviral therapy during primary infection."¹ According to Dr. David Ho, director of the Aaron Diamond AIDS Research Center, mathematical models suggest that patients caught early enough and treated with combination drug therapies could be free of HIV in two to three years.²

While complete eradication of the HIV virus from the body has not yet been demonstrated, combination drug therapies have proven effective for many, driving viral loads (the amount of virus in the blood) below detectable levels, and maintaining or dramatically improving overall health. Combination therapies can slow the progression from HIV to AIDS, and can help prevent opportunistic infections (OIs). For example, researchers at NIH's National Eye Institute recently discovered that a combination of protease inhibitors and other anti-HIV drugs can prevent or delay the progression of cytomegalovirus (CMV) retinitis, a common complication of AIDS which causes

¹ C. Carpenter, et. al., "Report of the NIH Panel to Define Principals of Therapy of HIV Infection," June, 1997.

² L. Altman, "With AIDS Advance, More Disappointment," *New York Times*, January 19, 1997.

blindness without proper treatment.³ Some patients in the study were able to stop standard CMV retinitis treatment, which can be cumbersome, toxic, and extremely costly (between \$50-100,000 per patient per year), without advancement of their disease.⁴

Combination drug therapies including protease inhibitors are expensive, with costs ranging from \$8,000 to \$10,000. But several studies have indicated that the dollars spent "up front" on these medications are offset by later savings on hospitalizations and other expensive care and treatment for AIDS-related illnesses. A study by Dr. Peter Ruane of the Tower Infectious Disease Medical Associates in Los Angeles found that each dollar spent on combination drug therapies resulted in at least two dollars of savings on overall treatment costs, which declined 23 percent.⁵ The same study reported a 57 percent drop in the average number of days patients spent in the hospital. Data from Saint Vincent's Hospital in New York support the conclusions of the Tower study, showing a significant decrease in inpatient care, both in terms of the number of people hospitalized and the average length of stay.⁶

The findings of the protease inhibitor studies—that early intervention and treatment can prolong health and reduce the need for more expensive treatment later—are consistent with earlier studies on the cost-effectiveness and beneficial impact of preventive treatment. Researchers at Johns Hopkins Hospital compared the outcomes of patients who received prophylactic treatment for the opportunistic infection *Pneumocystis carinii* pneumonia (PCP) with those who did not receive such treatment. The patients not taking prophylaxis accounted for all of the deaths attributed to PCP, 85 percent of the hospital days, 100 percent of the Intensive Care Unit days, and 89 percent of the inpatient charges. The study concluded that those "who developed PCP despite prophylaxis had a better outcome and used fewer resources than patients not receiving preventive therapy."⁷ Another study examining preventive treatment for PCP found that prophylaxis resulted in longer life and a savings of \$16,503 for each patient, as compared with no prophylaxis.⁸

³ NIH News Release, "Combination Drug Therapy for AIDS Found to Control Blinding Eye Infection," May 20, 1997 (reporting study results published in the *Journal of the American Medical Association*, May 21, 1997).

⁴ *Id.*

⁵ P. Ruane, "Dramatic Reductions in Use of Healthcare Services by Patients with HIV Result from Use of Combination Therapy with a Protease Inhibitor," Tower Infectious Disease Medical Associates, Inc., January 23, 1997.

⁶ R. Torres, "Impact of Potent New Antiretroviral Therapies on In-Patient and Out-Patient Hospital Utilization by HIV-Infected Persons," Saint Vincent's Hospital and Medical Center, January 23, 1997.

⁷ J. Gallant, et. al., "The Impact of Prophylaxis on Outcome and Resource Utilization in *Pneumocystis carinii* Pneumonia," *Chest*, April 1995: 1018-1023.

⁸ A. Castellano and M. Nettleman, "Cost and Benefit of Secondary Prophylaxis for *Pneumocystis carinii* Pneumonia," *Journal of the American Medical Association*, August 14, 1991: 820-824.

Comprehensive care and treatment which prevents or delays the progression from HIV infection to AIDS can both improve quality of life and save money. A survey of the costs of care for Medicaid patients with HIV in Baltimore found that monthly costs for people with CD4+ T-cell counts under 50 (generally a sign of more advanced HIV disease) were more than twice those of people with more than 500 T-cells.⁹ As noted above, spending money in the early stages of HIV disease for treatment with combination drug therapies can reduce more expensive interventions later. Yet under the present Medicaid system, many living with HIV must wait for their T-cells to drop and their illness to worsen before they can receive coverage and access care.

GAPS IN HEALTH CARE COVERAGE REMAIN

The advances in overall health care and drug treatments have brought renewed health and unprecedented hope to many people living with HIV disease. For the first time in the 15 years of the AIDS epidemic, there has been a decrease in the numbers of Americans dying from AIDS. The U.S. Centers for Disease Control (CDC) reported a 13 percent decline in the number of AIDS deaths for the first six months of 1996, as compared to the same period in 1995, and attributed this decline to improved medical care, prophylaxis for OIs, and the use of combination therapies.¹⁰

In the same report, however, the CDC noted that AIDS continues to be the leading cause of death of Americans aged 25 to 44, and that the "increased prevalence of AIDS [in the U.S.] indicates the need for medical and other services for persons with HIV infection." While the new medications make obtaining care more important than ever, challenges in expanding access to primary care and treatment remain.

Medicaid provides access to health care coverage for low income, uninsured, disabled people. Individuals who are HIV positive but have not been diagnosed with AIDS, however, are often not eligible for Medicaid, because they do not meet the program's disability standards or other categorical eligibility requirements. To qualify for Medicaid, people must meet income requirements and the disability criteria of the federal Supplemental Security Income (SSI) program. The Social Security Administration uses the CDC's definition of AIDS, along with evidence of functional impairments, as proof of disability.¹¹ **Despite the fact that early clinical intervention—including primary care, preventive services, and medication therapies—has**

⁹ R. Moore and R. Chaisson, "Costs to Medicaid of Advancing Immunosuppression in an Urban HIV-Infected Patient Population in Maryland," *Journal of Acquired Immune Deficiency Syndromes and Human Retrovirology*, 1997, 14:223-231.

¹⁰ Centers for Disease Control, *Morbidity and Mortality Weekly Report*, February 28, 1997, 46: 165-173.

¹¹ The CDC definition of AIDS for surveillance purposes is: documented CD4+ T-lymphocyte counts <200 per microliter or percent of total lymphocytes <14 percent or a variety of opportunistic infections.

been shown to improve health and delay the onset of expensive opportunistic infections, most HIV positive individuals must wait until they “get sicker” and develop AIDS before they can receive Medicaid.

This is particularly devastating because the populations in which HIV infection is increasing are the ones likely to enroll in Medicaid once their HIV infection becomes full-blown AIDS. The epidemic is growing fastest among groups which have traditionally been socioeconomically disenfranchised, including racial and ethnic minorities, injection drug users, and women. In 1996, for the first time, blacks accounted for more AIDS cases than whites (41 percent versus 38 percent).¹² Women represented 20 percent of new AIDS cases in 1996, up from seven percent in 1985. While overall AIDS deaths declined 13 percent in the first half of 1996, deaths among women increased by three percent.¹³

These populations are also the groups less likely to have health insurance and access to treatments, and more likely to face barriers in obtaining health care, according to a survey by the Agency for Health Care Policy and Research.¹⁴ People who are uninsured or underinsured not only lack access to expensive combination therapies, but also to basic primary care and preventive services. Without insurance, people are more likely to wait until they have serious health problems before seeking care—problems which are then more expensive to treat. At this point, people would likely become eligible for Medicaid, but it is both inefficient and inhumane to require people to progress to an advanced stage of illness when we could offer access to effective and less costly care and treatment at an earlier time in the disease.

A Medicaid expansion also promotes public health, by giving uninsured and underinsured people with HIV an opportunity and an incentive to enter care earlier. Reaching people who would not otherwise have contact with health care systems provides the chance to teach and reinforce behavior changes which can prevent HIV transmission. [Reducing viral load through the use of combination drug therapies may also reduce infectiousness, although there is not yet conclusive scientific data on this issue.] The ongoing primary care and medical case management funded through Medicaid helps support patients in following complex treatment plans. If patients do not strictly comply with their combination therapy regimens, they are likely to develop drug-resistant strains of HIV. The existence of such drug-resistant HIV mutations may further complicate public health efforts to combat AIDS.

Despite the existence of federal AIDS programs, such as the AIDS Drug Assistance Programs (ADAPs) and the other components of the Ryan White CARE Act, Medicaid serves as the

¹² Centers for Disease Control, *Morbidity and Mortality Weekly Report*, February 28, 1997, 46: 165-173.

¹³ *Id.*

¹⁴ P. Mohr, Patterns of Health Care Use Among HIV-Infected Adults: Preliminary Results,” *AIDS Cost and Services Utilization Survey*, Agency for Health Care Policy and Research, September 1994: 3.

foundation of AIDS care through its provision of both comprehensive health care and drug therapies. ADAPs provide limited prescription drug coverage for some uninsured and underinsured people with HIV and AIDS. But these programs cannot (and are not designed to) meet the need for comprehensive primary care and diagnostic services. In spite of their limited mission—to provide access to a limited formulary of proven AIDS medications—ADAPs face severe financial pressure in many states, and often cannot meet the growing demand for new combination therapies. In some states, ADAPs do not even cover protease inhibitors, and many offer a very limited formulary of antiretroviral and OI drugs. In other states, there are lotteries, long waiting lists, and increasingly restrictive eligibility criteria for ADAP participation.

While other Ryan White CARE Act programs pay for some primary care and drug reimbursement, they are not intended to provide widespread comprehensive health care. Ryan White funding is used for a range of care and services, including food, transportation, and case management for people living with AIDS. Additionally, many ADAPs and Ryan White-funded primary care programs have eligibility criteria which exclude people in the earlier stages of HIV disease. These programs lack the financial resources to broaden their eligibility criteria to cover such individuals.

Even if a person with HIV were able to obtain medications through an ADAP or Ryan White program, without primary care and services like medical case management, it is impossible to monitor that person and assure that the prescribed treatment regimen is appropriate and effective. An expansion of Medicaid can provide such care and services.

Some may question whether it is appropriate to have a disease-specific expansion of Medicaid, even as a demonstration project. We believe that it serves the interests of public health, scientific knowledge, and fairness to broaden Medicaid coverage to include people with HIV.

Public health: With earlier health care and treatment, as mentioned above, people living with HIV are more likely to avoid behaviors which can spread the virus, and are more likely to adhere to complex treatment plans, which can both prolong health and prevent development of drug-resistant strains of HIV.

Scientific knowledge: Protease inhibitors and other new medications received rapid FDA approval, have not yet been in long-term use, and have been researched mainly by studying people in more advanced stages of HIV disease. There are many remaining questions about the benefits, risks, and best way to use combination therapies in people who are HIV positive, but do not have AIDS. A Medicaid expansion demonstration project which brings people with HIV into care provides the opportunity to gather data and conduct research studies designed to answer these questions.

Fairness: The current Medicaid system requires most people with HIV to develop AIDS in order to gain access to health care and new combination therapies. This is unfair and inhumane, especially when the government provides treatment for other communicable

diseases, such as sexually transmitted diseases and tuberculosis. Principles and guidelines recently released by the Department of Health and Human Services and the NIH call for earlier intervention with combination drug therapies as the standard of care for the treatment of HIV in most cases. The government should ensure that this standard of care, endorsed by its own agencies, is accessible to those who have no other way to obtain it.

The Medicaid eligibility framework—requiring total disability to qualify for coverage—is at odds with current clinical and public health knowledge. Many low income HIV positive individuals with relatively intact immune systems are not presently eligible for Medicaid, but will eventually qualify for Medicaid after developing AIDS. Unable to afford adequate treatment early in their HIV disease, they cannot obtain the range of health care services necessary to manage the disease, and will be more ill when they do enroll in Medicaid. Ironically, earlier access to these medical services and treatments would enable them to preserve their health, learn how to prevent transmission of HIV to others, and avoid more costly care such as inpatient hospitalization. For humane, financial, and public health reasons, it is time to make Medicaid's eligibility requirements consistent with the clinical realities of HIV disease.

A COLLABORATIVE RESPONSE

In response to the contradictions between current Medicaid disability criteria and AIDS clinical evidence and care standards, which call for early treatment of HIV disease, representatives from the AIDS Action Council, community-based AIDS service organizations, the Health Care Financing Administration (HCFA) and the Office of Management and Budget (OMB) have begun to work collaboratively to address these issues. Response from the administration has been unequivocally supportive, culminating in endorsements from Vice President Al Gore, who has asked HCFA to find ways in which to expand Medicaid and allow more low-income Americans with HIV to access care and therapies. Gore is quoted as saying “[Medicaid expansion] can ease suffering, it can increase hope, and it can get new drug therapies into the hands of people who need them.” As a result of these collaborations, we are all working together under HCFA's leadership to develop a plan for expanding eligibility to Medicaid for persons who are HIV positive.

PROPOSAL DESIGN

The objective of this program is to expand Medicaid eligibility to low-income individuals who have tested positive for the presence of HIV and who would be otherwise eligible for Medicaid once their health status met an AIDS-defining diagnosis. States participating in this initiative will demonstrate that the provision of earlier access to care and treatment will extend the period of time that a person who is HIV positive remains asymptomatic, defer the onset of opportunistic infection, and delay hospitalization, all of which will result in significant cost savings and life-enhancing benefits. The following section describes what we believe are the core components of this initiative.

Eligibility

Any and all individuals who meet the following criteria will be eligible under this program:

- test positive for the presence of HIV; and
- have income at or below 200 percent of the federal poverty level.

State demonstrations will coordinate resources with other private, state, and federal programs. Individuals with private insurance can apply for and become eligible for Medicaid as a “wrap around benefit” thereby maximizing private insurance participation. State proposals will specify the state specific eligibility guidelines and coordination of other state and federal programs.

Covered Benefits

Ideally, states will provide the full benefit package (i.e., mandatory and optional Medicaid services) to individuals eligible through this program. In any case, benefit packages must be flexible to accommodate new treatment advances and changes in standards of care that become available during the course of the demonstration. Through this project, states, at a minimum, must provide:

- primary care,
- prescription drugs,
- diagnostic and laboratory services,
- mental health services, and
- substance abuse treatment services.

Options to Participate in the Demonstration Projects

Section 1115 of the Social Security Act allows the Secretary of Health and Human Services to grant waivers from the usual federal Medicaid requirements¹⁵ to states which want to create demonstration projects to test new approaches to Medicaid. These demonstration projects must be designed to promote the objectives of Medicaid,¹⁶ and must include a research and evaluation component. Generally, demonstration projects created under a Section 1115 waiver are supposed to be “budget neutral” over the life of the project, meaning that costs under the demonstration project do not exceed what costs would have been without the waiver in place. Section 1115 also authorizes matching federal funds for certain expenditures.

¹⁵ As defined in Section 1902 of the Social Security Act, and other provisions incorporated through Section 1902.

¹⁶ As set out in Title XIX of the Social Security Act.

This initiative will be designed to provide states with the maximum flexibility possible in participating in a Medicaid expansion demonstration project. The project does not necessarily need to meet the traditional definition of "budget neutrality," since there can be federal and/or state subsidies. Also, budget neutrality should be measured within a time frame which is appropriate for assessing the clinical impact and cost-effectiveness of the new combination therapies (e.g., over a period of five to ten years).

Options for participation include the creation of a free-standing demonstration program or new or amended 1115 waivers. New 1115 waivers could provide the vehicle to expand Medicaid eligibility and/or allow a Medicaid buy-in option for those individuals otherwise ineligible for coverage. Amending an approved or pending 1115 waiver could also be used to expand eligibility. In addition, states could increase the income standards for their Medicaid buy-in programs, allowing more persons who are HIV positive to qualify. For example, states could set the income standard at 200 percent of the federal poverty level or they could use a graduated system to make more individuals eligible.

NEXT STEPS

Over the next several months, the AIDS Action Council will work with HCFA to develop and refine a solicitation process for states to successfully participate in the HIV Expanded Eligibility Demonstration Initiative. It is important for community-based AIDS service organizations to urge their state governors and Medicaid directors to advocate for this initiative with HHS and HCFA. While we expect that this initiative will offer states tremendous opportunities to provide cost-effective access and coverage to its most vulnerable populations, we also recognize the range of development and design issues that need to be resolved. Over the next several months, the AIDS Action Council will work with states and HCFA to complete the following tasks:

- Continue to work with HCFA to design a program that includes adequate incentives for state participation in this initiative.
- Build consensus among federal and state leadership, elected officials, and government staff, including representatives from Medicaid programs, Departments of Health, and Departments of HIV Services.
- Work with HCFA to develop a process that allows states to efficiently design and implement a vehicle for eligibility expansion that responds to the unique environment and situations of each state (waiver amendment or new waiver submission).
- Design a process to solicit input from consumers, AIDS service organizations, primary care and other health care providers, and [health care ?] agencies regarding program design and program effectiveness, on an ongoing basis.

- Work with HCFA to develop a methodology that allows states maximum flexibility in measuring cost effectiveness. The goal will be to have HCFA resolve methodology issues related to baseline measurements, the measurement of savings in other government programs, and evaluation time frames.
- Work with HCFA to identify and develop data bases that provide the information needed to estimate current expenditures and projected costs for the purposes of assessment and future planning. Necessary data includes the number of newly eligible individuals by state and service area (persons who are HIV positive with incomes below state defined eligibility criteria), utilization of services, and cost.

until it's over
AIDS ACTION

ALERT

May 20, 1999...www.aidsaction.org... Contact: Francesca Fragomeni - 202-986-1300 x3071 - network@aidsaction.org

Issue 1: Work Incentives Bill Sails Through House Commerce Committee

The **Work Incentives Improvement Act (H.R. 1180)**, which now has 157 cosponsors, was approved yesterday by voice vote in the full House Commerce Committee. No amendments were offered to the legislation. This step is truly a victory in moving this important bill further along the legislative road toward final passage. However, one crucial step remains before **H.R. 1180** can be considered by the full House: it must also be approved by the House Ways and Means Committee. Furthermore, the bill's Senate companion, **S. 331**, is still awaiting floor debate by the full Senate, as Senator Trent Lott (R-MS) has not yet scheduled the bill for consideration, and has indicated his strong opposition to the Medicaid Demonstration Program, which would extend Medicaid coverage to workers who have a disability such as HIV/AIDS.

Take AIDS Action:

1. Contact the House Commerce Committee (members listed below) to thank them for their favorable vote at the markup and for their support of **H.R.1180**.
2. Contact members of Congress serving on the House Ways and Means Committee (listed below) and urge them to support **H.R.1180** as passed by the House Commerce Committee.
3. Contact Senator Lott's office to urge him to bring **S.331** to the Senate floor for full debate.
(Phone: 202/224-6253, Fax: 202/224-2262)

House Committee on Commerce:

Thomas Bliley, (R-VA) - Chairman

Republicans:

Joe Barton, TX
 Brian Bilbray, CA
 Michael Bilirakis, FL
 Ed Bryant, TN
 Roy Blunt, MO
 Richard Burr, NC
 Tom Coburn, OK
 Christopher Cox, CA
 Barbara Cubin, WY
 Nathan Deal, GA

Robert Ehrlich, MD
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 Greg Ganske, IA
 Paul Gillmor, OH
 James Greenwood, PA
 Steve Largent, OK
 Rick Lazio, NY
 Charlie Norwood, GA
 Michael Oxley, OH
 Charles Pickering, MS

James Rogan, CA
 John Shadegg, AZ
 John Shimkus, IL
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Democrats:

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 Sherrod Brown, OH
 Diana DeGette, CO

Lois Capps, CA
 Rick Boucher, VA
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John Dingell, MI
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 Bart Gordon, TN
 Karen McCarthy, MO
 Edolphus Towns, NY
 Gene Green, TX

Frank Pallone, NJ
 Henry Waxman, CA
 Edward Markey, MA
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House Committee on Ways and Means:

Bill Archer, (R-TX) - Chairman

Republicans:

Philip Crane, IL
 Bill Thomas, CA
 Clay Shaw, FL
 Nancy Johnson, CT
 Amo Houghton, NY
 Wally Herger, CA
 Jim McCrery, LA
 Dave Camp, MI

Jim Ramstad, MN
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 Mac Collins, GA
 Rob Portman, OH
 Philip English, PA
 Wes Watkins, OK

J.D. Hayworth, AZ
 Jerry Weller, IL
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 Ron Lewis, KY
 Mark Foley, FL

Democrats:

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 William Coyne, PA
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Jim McDermott, WA
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 John Lewis, GA
 Richard Neal, MA
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William J. Jefferson, LA
 John Tanner, TN
 Xavier Becerra, CA
 Karen Thurman, FL
 Lloyd Doggett, TX

(NOTE: Issue #2 on following page...)

Gore Urges Expanding Medicaid to Include Not Just AIDS, but HIV Patient

By Judith Havemann
Washington Post Staff Writer

The Clinton administration is exploring ways to provide free health insurance coverage to large groups of poor Americans who have the virus that causes AIDS but have not yet developed the disease.

By expanding the eligibility requirements of Medicaid, the administration argues that it can save both lives and money because individuals infected with HIV could receive new drug therapies that would postpone their need for costly hospital care.

Roughly 775,000 Americans have the virus, and another 216,000 have AIDS. AIDS patients must now be disabled before they

can qualify for Medicaid, the health insurance program for the poor. By making new drugs and other therapies available much earlier, the government would attempt to prevent them from developing full-blown AIDS.

"The expanded coverage can ease suffering, renew hope, and ensure that good people are not priced out of life-saving medicine," Vice President Gore announced to an AIDS Action dinner on Wednesday.

He directed federal health officials to determine the feasibility of expanding Medicaid coverage within the next 30 days.

Medicaid is financed jointly by federal and state governments. Eligibility requirements differ from state to state, but all Medicaid

recipients have low incomes. Under the plan the administration is exploring, each state would have the option of deciding for itself whether to participate in any possible Medicaid expansion for people with HIV.

Bruce Bullen, head of the National Association of State Medicaid Directors, said many states may see the value of providing preventive coverage to people with HIV. But, he added, while the additional costs would be immediate, the savings would be long term.

More importantly, he said, the Medicaid program is "inflexible" and would require states to offer not just drugs to people with HIV, but the entire range of Medicaid services offered—from unlimited home health

care to personal care to hospital care. "The problem is the entitlement nature of the program and the all-for-nothing benefits," said Bullen.

The introduction of potent new drugs that offer the potential to slow or even reverse the progress of AIDS in some patients has triggered the push for the unprecedented expansion of Medicaid to individuals infected with a virus but not yet sick. Some of the drugs cost between \$10,000 and \$15,000 a year, making them unaffordable to many who need them.

But an increasing number of other diseases are also being treated with promising but expensive new drug treatments that many patients cannot afford.

Arthur Caplan, a bioethicist at the University of Pennsylvania, said that while he supports extending the benefit of the new AIDS drugs to as many people as need them, "This disease, by disease strategy, is not fair and equitable."

Other diseases, he said, do not have the "lobbyists, the voice, the visibility, that those in the AIDS community are able to muster."

Caplan said the AIDS community should use its lobbying might to help poor people with all sorts of diseases get the treatment they require. Otherwise, he said, "those who are weaker, more ignorant, less politically savvy and less mediagenic will continue to fall by the wayside."

Administration Offers Compromise to Europeans Over Helms-Burton Act

By Thomas W. Lippman and Paul Blustein
Washington Post Staff Writers

In an effort to avert a bruising trade dispute with the European Union, the Clinton administration is offering to seek modification of the Helms-Burton Act in exchange for European efforts to discourage some types of investment in Cuba. Senior administration officials have begun briefing key members of Congress on the proposed deal, which calls for the European Union to suspend for six months its complaint against the United States in the World Trade Organization (WTO), according to sources who heard the briefings.

In broad outline, the administration plan calls for the Europeans to "establish disciplines to deter" private companies in Europe from investing in property confiscated without compensation, not just in Cuba but globally. In exchange, Congress would be asked to relax

some provisions of Helms-Burton, the U.S. law that imposes sanctions on foreign companies that "traffic" in confiscated property in Cuba.

The European Union, which strongly opposed Helms-Burton as an unjustifiable effort by the United States to impose its anti-Cuban policies on others, has filed a formal complaint with the WTO, which was established with strong U.S. support to adjudicate international trade disputes.

The Clinton administration, however, has refused to accept WTO jurisdiction, arguing that Helms-Burton is not a trade dispute but a national security issue, and it called on the European Union to withdraw the complaint. But the Europeans have pressed ahead and are scheduled to file their first brief on Monday.

Administration officials, European diplomats and congressional staff members said it is unlikely that any agreement can be reached before then.

"It is extraordinarily premature to talk about any imminent agreement because there are major issues which still divide us," said Commerce Undersecretary Stuart Eizenstat, who was assigned last year by President Clinton to seek an accommodation with Europe on the Helms-Burton issue.

Two provisions in particular of the Helms-Burton law have aggrieved Europe and Canada. One would permit U.S. citizens to sue in U.S. courts any foreign company that profits from trafficking in confiscated property in Cuba. To assuage the allies, President Clinton twice has waived this provision and said he plans to continue to waive it every six months.

The second provision calls for the exclusion from the United States of executives of such foreign companies. Canadian and Spanish executives have been denied visas under this provision, which under Helms-Burton cannot be waived. Under the administration's plan, Con-

gress would be asked to modify this section of the law if the Europeans adopt across the board the principle that corporations not be allowed to profit from investing in properties confiscated without compensation.

Initial reaction to the administration plan was cautious. One key Republican legislative aide said any effort to police claims of noncompensation in countries other than Cuba would be so controversial and contentious that it has little chance of adoption.

"We thought about it," he said, "till somebody asked about Palestinian claims against Israel."

A diplomat from an E.U. country said his government would not endorse the administration proposal because it would expand a principle his government does not accept—that of trying to prevent private companies from making investments wherever they choose.

But Marc Thiessen, spokesman for Senate

Foreign Relations Committee Chairman Jesse Helms (R-N.C.), one of two main sponsors of the Helms-Burton Act, welcomed the proposal.

"Our goal all along was to achieve the globalization of the Helms-Burton principle, which is that you don't traffic in confiscated property," Thiessen said. Helms has long been interested in the compensation issue, pressing countries such as Nicaragua where left-wing regimes seized property to restore the property or compensate the owners.

"We're not giving up anything" during the proposed six-month negotiating period, Thiessen said. "We've not been asked to dilute Helms-Burton in any way, nor would we be inclined to do so."

FOR MORE INFORMATION 
To read the full text of the Helms-Burton legislation, click on the front page of The Post's Web site at www.washingtonpost.com

The Washington Post

FRIDAY, APRIL 11, 1997

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THE WALL STREET JOURNAL
THURSDAY, JULY 11, 1996

Costly New AIDS Drug Therapy Finds Support In Congress, Due to Efforts of Unlikely Alliance

By CHRISTOPHER GEORGES

Staff Reporter of THE WALL STREET JOURNAL
WASHINGTON — As scientists hail a promising — but extremely costly — new AIDS drug therapy, an unlikely alliance of left- and right-leaning AIDS activists and pharmaceutical companies is busy lobbying Congress for more money to pay for the treatments.

And in a year of budget squeezing, it is finding surprising success. At first people said that a Republican-controlled Congress wouldn't care about AIDS. That has not been the case, says Bill Arnold, who heads one lobbying group. "Conventional wisdom has been proven wrong."

The huge long-term costs of the new treatment worry federal and especially state officials. But Republicans and Democrats in Congress are now expected to boost federal spending to help uninsured patients buy AIDS drugs by an additional \$23 million to \$100 million, on top of nearly \$400 million in the current 1996 fiscal year. Congress and the White House already agreed to raise this year's spending specifically for the AIDS Drug Assistance Programs, or ADAP, by \$52 million.

The increased funding is in part a result of stepped-up lobbying efforts by AIDS

AIDS Treatment Advances

Combining two new AIDS drugs sharply augments the antiviral punch of each, early trials show. Meanwhile, other breakthroughs are revitalizing the market for Glaxo Wellcome's older AIDS drugs. Articles on Pages B3 and B1.

activists and gay-rights groups including the gay-rights Log Cabin Republicans. Indeed, the influence of these groups has grown with their ability to raise and distribute political contributions. Combined, nearly a dozen such groups — led by the Human Rights Campaign Fund, supporting mostly Democrats, and by the Log Cabin Republicans — now give nearly \$500,000 annually to congressional candidates, according to the Center for Responsive Politics, a Washington watchdog group.

"In the past, some offices just didn't want to see you," says Winnie Stachelberg, of the Human Rights Campaign. "I'm sorry, they'd say, 'We can fund bridges and defense, but not AIDS-related programs.' That's rare now." Indeed, many congressional offices now have staff dedicated full-time to gay rights and AIDS-related issues.

Industry Allies

AIDS activists credit Log Cabin Republicans with helping to open GOP doors on Capitol Hill. In return, the organization has emerged as a tireless cheerleader for the Republican effort in this area, even pushing the argument that programs such as ADAP are closely aligned with the new GOP ideology. "Without these programs,

people will be forced onto welfare. By Republican principles, you don't do that," says James Driscoll, a policy adviser for the organization.

Key allies in the effort to increase AIDS-related drug-treatment funding, especially in nudging Republicans, have been pharmaceutical companies, which stand to benefit greatly from wider use of the new treatments they are developing. These include Roche Holding Ltd.'s Hoffmann-La Roche Inc. U.S. unit, Abbott Laboratories Inc. and Merck & Co. Historically one of the most generous industries in terms of political contributions — donating more than \$3.3 million last election cycle — they have agreed to combine their lobbying efforts with AIDS activists. For example, they signed on to the ADAP Working Group, an organization of more than 100 AIDS activist groups, state health officials and drug companies.

"Their ties with Republicans have been extremely helpful," says Mr. Arnold, who heads the group. Drug-company lobbyists, he says, "already have a level of trust established with Republicans that otherwise might not be there."

Lawmakers from both parties also agree that liberally funding programs that supply the new drugs — even if their promise is based on hopeful thinking — makes fiscal sense. Though costs run now upwards of \$10,000 a person a year for the new three-drug cocktail, that's a fraction of the amount needed to pay for acute care and other services for hospitalized AIDS patients, much of which is ultimately paid by taxpayers through Medicaid.

Still, as science races forward, other funding problems are emerging. Many predict that the current funding levels for AIDS drug therapies may be just a fraction of amounts soon needed. Perhaps most worrisome, some state governments, facing fiscal constraints and fearful of the high potential costs of the new drugs, have been reluctant to start uninsured patients on them.

Costs Are 'Astounding'

"The costs associated with the new drugs are so astounding that some states are locked into inertia," says Joseph Kelly, deputy director of the National Alliance of State and Territorial AIDS Directors. "There is a fear they will be forced to cut them off or force them onto welfare to guarantee coverage," he says.

The new drugs, known as protease inhibitors, for many patients remove all detectable signs of HIV, the AIDS virus, from the blood. In recent months, and especially at this week's 11th International Conference on AIDS in Vancouver, British Columbia, scientists have been particularly upbeat about the prospects for the new therapy. But currently, treatment per

patient costs as much as \$16,000 a year, which would ultimately mean a cost of billions of dollars annually to supply most Americans infected with the virus.

States are already being asked to bear some of the burden. Altogether they now voluntarily contribute about one dollar for every three federal dollars. But while the federal government supplies funds, states decide on their own whether to pay for the new protease inhibitors. The generosity has been limited to a handful of states, such as New York, California and Maryland, all of which are likely to allocate millions of dollars in supplemental funds for next year.

But states such as Florida have thus far declined to add the new drugs to their list of covered drugs, in part out of fear they will quickly bankrupt their entire AIDS-relief program. That threat is real. Last year, 20 states ran out of money before year end, making it through only after the federal government stepped in with emergency funds.

As a result, states are moving slowly. "It's a disaster here in Illinois," says Mark Ishaug of the AIDS Foundation of Chicago. The Illinois Legislature, facing a budget crunch, recently voted to freeze levels of state spending on AIDS drug-treatment programs for next year while also tightening eligibility and limiting to 28 (down from 110) the number of AIDS drugs it would help pay for. Meanwhile, AIDS clinic workers there say they expect the number of people requesting the new drugs to soon double.

Most experts agree that at least some uninsured AIDS patients who can't get access to ADAP funding for the new drugs will have no recourse except to spend down their savings to become eligible for Medicaid, which is now required by federal law to cover the new drugs. But this would do little to ease the states' funding burden, as they are required to also help pay for this program. Currently ADAP supplies drugs for about 15% — or about 70,000 — of all AIDS patients, all of whom are uninsured but not poor enough to qualify for Medicaid, which now spends \$3.6 billion annually on AIDS treatment and drugs.

At the same time, AIDS activists, while in general praising GOP efforts for bolstering ADAP funding, are harshly critical of the Republican effort to overhaul Medicaid. The restructuring, which passed Congress but was vetoed by President Clinton, would allow states to deny the new drug therapy. Republicans contend states would step up and pay for the new treatments for its poorest patients.

ADAP funding for the new drugs will have no recourse except to spend down their savings to become eligible for Medicaid, which is now required by federal law to cover the new drugs. But this would do little to ease the states' funding burden, as they are required to also help pay for this program.

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The Boston Globe

WEDNESDAY, OCTOBER 8, 1997

Medicaid's outdated AIDS policy

Life expectancies for people infected with the AIDS virus continue to improve thanks to early detection and treatment with expensive new combination drug therapies using protease inhibitors. Recognizing this, the National Institutes of Health have issued new guidelines calling for earlier treatment of HIV infections. But the government's own requirements for Medicaid coverage of AIDS conflict with these principles. It is time for the Clinton administration to make good on a promise to extend Medicaid coverage to eligible patients at the earliest stages of the disease.

Under current Medicaid regulations, patients are not eligible for coverage unless they meet low-income requirements and qualify for one of the disabilities covered by the federal government's Supplemental Security Income program. Early infection with HIV - the stage at which protease inhibitors are most effective - is not on the list. Rather, an infected individual must wait to develop full-blown AIDS to qualify for Medicaid. By that time the immune system is often compromised.

There is no question that expanding Medicaid so that more HIV-infected patients can get access to the protease inhibitors will be expensive: Costs range from \$8,000 to \$10,000 a year for the drugs alone, and many thousands more people would qualify. But dollars spent up front on these medicines save enormous sums down the line in hospitalization. Medicaid coverage varies from state to state, but at a minimum it should include the cost of the drugs, lab tests, and support services needed to maintain the strict drug regimen; primary care to avoid simple infections that can be life-threatening; and substance-abuse treatment, which accounts for increasing numbers of AIDS cases in the first place. A conference on access and ethics in the new AIDS landscape takes place at the Kennedy Library today.

In April, Vice President Gore ordered the Health Care Finance Administration to devise a plan to extend Medicaid to HIV-infected patients within 30 days. It shouldn't take so long for the bureaucracy to catch up with medical progress.

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LEVEL 2 - 20 OF 43 STORIES

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SECTION: OUTLOOK; Pg. C01

LENGTH: 2322 words

HEADLINE: When You Want to Live, But Can't Afford It; Hit-and-Miss AIDS Care on the Margins

BYLINE: Amy Waldman

BODY:

On one wall hangs the hard reality: A small, hand-stitched quilt commemorating the members of the District's homeless community lost to AIDS. With the quilt, Health Care for the Homeless, which established this day center in a Northeast strip mall for the city's HIV-positive homeless, mourns its dead. Last year's tally: 42.

On another wall hangs the hope: A sign listing "Rules for Protease Inhibitors." The reference is to the new AIDS drugs that, in "combination therapy" with older medications, are transforming AIDS into a disease that while not yet curable, is at least containable -- one that can be lived with. Between the two walls, men play pool and foosball, make art or small talk.

Which tableau reflects their destiny is a matter of chance -- and social compassion.

The denizens of this center have what one doctor calls "special barriers to treatment" -- no money, no home, no family, quite often a drug or alcohol-filled history and mental illness to boot. Their situations are extreme, but there are plenty of people with some measure of their circumstances. HIV has a mainstream -- insured, educated gay white men; and it has margins -- the poor and homeless and minorities, the drug addicted and mentally troubled. So while discussion of combination therapy's potential is often scientific -- some people's systems respond to protease inhibitors, some don't, no one knows why -- socioeconomics ultimately may have as much to say as biology about who benefits from this and other medical breakthroughs.

The problem is not that the poor or uninsured have no access to care and medication, including the pricey protease inhibitors. The problem is that the access is so unpredictable, so labor-intensive -- so capricious. Doors open and close, programs start and stop, hope is parceled out. By lacking the will to change that, we sanction the role of randomness in people's chances of recovery. Morality aside, evening out and extending coverage makes economic sense, too: Study after study has shown that treating HIV and AIDS early and aggressively saves money.

Because more than half of those with AIDS rely on the Medicaid program for the poor, and many more have no insurance at all, the disease offers a case



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study in the vagaries of American health care, and a snapshot of the holes in the social safety net. The system's patchwork nature is well-conveyed by the fact that every doctor or social worker seems to have a different frustration in their attempts to provide their poorer patients with the newest, most sophisticated treatments for AIDS.

At the day center, for example, the Holy Grail of treatment is the viral load test, a relatively new way of measuring the level of infection. The traditional measure of illness, the T-cell count, indicates only how equipped your body is to fight disease. A viral load tells you how much disease there actually is -- a more accurate gauge of mortality's proximity. The test, which ought to be done at least every three months, also reflects changes in the body more quickly than a T-cell count, thus allowing treatment to be adjusted. But a viral load test costs at least \$ 80 and can be as much as \$ 300, and the center hasn't been able to get them through Medicaid. "Poor people don't have the same opportunity to get the viral load as rich people, and their quality of care is enormously diminished," Doug Morrison, the head of the day center, says with unconcealed frustration.

The immediate future is brighter: Whitman-Walker Clinic has obtained a federal grant to provide D.C. residents with viral load tests, and Medicaid may begin covering them sometime this year.

In many instances, however, the system seems more mercenary than merciful. Getting on Medicaid, for example, is not as simple as proving your poverty; there are medical criteria as well, which have gotten stricter as the numbers with HIV have grown. Having the AIDS virus isn't enough; having a T-cell count below 200 isn't either, though it once was. You must have had at least one opportunistic infection, sometimes more. "You have to be pretty darn disabled to qualify," says Roxanne Cox-Iyamu, director of medical resources at Whitman-Walker.

If you do qualify for Medicaid, you can get medicine not just to prevent opportunistic infections, treat high blood pressure, etc. -- but also protease inhibitors. That's no small thing: Combination therapy costs at least \$ 10,000 annually -- indefinitely.

That figure is most troubling for those caught in the middle -- uninsured and Medicaid-eligible. This is the limbo inhabited by the working poor or middle class, those denied insurance with their job and unable to buy it. It's a yawning gap: At D.C. General Hospital's HIV/AIDS clinic, for example, approximately two thirds of the 900-patient population falls into that category; at Whitman-Walker, two-thirds of the 1,500 patients. For them, protease inhibitors and other expensive new medications are like fruit to Tantalus -- within sight, but not necessarily within reach.

Care for the uninsured is paid for mainly by the federal Ryan White CARE Act, which provides grants to clinics and hospitals; it is also the primary funder of states' AIDS Drug Assistance Programs (ADAP), which provide medications for the uninsured and Medicaid-eligible. In the District, ADAP had always been fragile, prone to temporary shutdowns when funds ran low, but it buckled when word began to spread about protease inhibitors in mid-1996. In June of last year, ADAP was spending \$ 6,466 per day on drugs. In July, daily spending soared to \$ 8,460. By August, it was at \$ 9,387 per day and the program went into



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"cost-containment" mode. No District resident has since been able to start on protease inhibitors through the program; and ADAP had to establish a waiting list -- now 113 names long -- even for the drugs it still provides.

So what to do if you want to live but can't afford it? Throw yourself on the mercy of the four pharmaceutical companies who make protease inhibitors. Each company has some form of support or indigent patient program to provide the drugs to uninsured patients. Merck & Co., which makes the protease inhibitor Crixivan, has given the drug to some 10,000 people in the United States, even as it strives to help them to find coverage through Medicaid or their local ADAP program. "It was a given that in this field it was critical to provide temporary assistance," especially given the gaps in coverage the uninsured face, says Michael Seggev, a company spokesman.

But charity can work -- or not work -- in mysterious ways. The companies don't release their income criteria for eligibility, and while several local doctors said they had never had a patient application denied, Prinzi Kumar, an assistant professor of medicine in Georgetown University Medical Center's Infectious Disease Division, says that eight of every 10 patients of hers who have applied have been rejected.

Kumar's desperate need to fill in the gaps has prompted morbid ingenuity: "When patients die we ask their families to bring in their [leftover] supply of protease inhibitors," she says; she also calls on patients who prove intolerant to the drugs. But such scavenging can't guarantee a sufficient supply.

For anyone who has HIV or AIDS, staying well is a lot tougher than getting sick was -- a moment of carelessness with a lover or needle compared to a lifetime of taking pills, monitoring vital signs. But imagine trying to do that without a fixed address or its accoutrements -- a pill box to store your medicines in, a calendar to remind you of doctors' appointments. Imagine being told that you must take your medicine on a full stomach, knowing that if your children are to eat three meals, you may not be able to. Imagine trying to answer to one narcotic taskmaster -- your medications -- even as another -- your 12-year drug habit -- angles for your soul. Imagine being unable to read the litany of instructions with your medication.

Lacking the ballasts of stability -- home, food, family, routine -- makes any treatment tenuous, but none more so than combination therapy. The pills demand a carefully clocked regimen: Martin Vasquez, a Mount Pleasant resident on triple-drug combination therapy, wearily spells out his daily routine of Crixivan and two other anti-retrovirals: two pills upon waking at 7 a.m., another two at 8 a.m, yet another at 9 a.m.; repeat in the afternoon after lunch; then take two more pills before bedtime. He is lucky -- he takes only 12 pills a day. Benjamin Norris, an HIV/AIDS outreach worker, says he takes 45 pills a day: protease inhibitors; two other antivirals; medicines to prevent infection, for pain, for peripheral neuropathy; vitamins.

Erraticism can be fatal: Take protease inhibitors incorrectly, or start and stop, and you may develop a strain of HIV resistant to all known treatments -- a strain you could spread. Doctors, therefore, must decide whether patients can be "compliant," based on their ability to keep appointments or take other medications.

Even when doctors decide to proceed with protease inhibitors, they watch



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nervously, knowing that discipline doesn't come naturally to people more accustomed to dissoluteness. "Don't take a drug holiday," warns the first on the list of protease inhibitor rules at the day center. Simple ignorance can be life-threatening, too: Vasquez, who works as an outreach worker at La Clinica del Pueblo in Mount Pleasant, recounts watching, horrified, as a friend downed a day's dose of protease inhibitors all at once, instead of spacing them correctly. "He said, 'That's the way I do it,'" Vasquez recalls.

Among the underfed and overcrowded, and in homeless shelters in particular, there is the added danger of tuberculosis. While TB rates are dropping nationwide, they are increasing in the District -- by 36 percent last year -- and one third of District residents with confirmed tuberculosis also have HIV. You can't take protease inhibitors and the TB medicine at the same time, so if a patient contracts TB after starting on combination therapy, he's facing an enforced drug holiday -- and, potentially, lethal resistance.

Yet inadequate funds, and the District's poor administration of the funds it does have, mean there are few services to move people into the mainstream. There is a severe shortage of affordable housing for people with AIDS, for example -- a situation aptly symbolized by the fact that those vying for the limited housing placements must compete in an annual lottery.

For addicts, the threat of relapse is a constant undertow threatening to pull them down and out. But, in the words of Beverly Jones, a case worker at the day center, "In this city there are so few substance abuse programs it's almost a joke." The ideal is to move people from short-term detox programs into in-house treatment -- thus removing them from drug-infested shelters and streets -- but the slots aren't there. "We refer and refer and refer," Jones says, "knowing people will probably not get in."

Caregivers, advocates and social workers for the poor, meanwhile, struggle to help uneducated and sometimes mentally ill patients navigate the byways of care. Fred Pardo, a social worker at D.C. General, notes that he is providing help with housing, finances and SSI benefits, transportation to medical appointments, child care, health education not to the 50 or 60 clients that the Agency for HIV/AIDS recommends for each social worker -- but to 109. With that load, he has only one chance -- the initial assessment -- to teach a patient the ABCs of HIV: nutrition, medication, the disease's progression, what can be done to outsmart it.

Whether someone doesn't start on combination therapy or any other treatment because they can't afford it or their lifestyle can't countenance it, the result is the same -- a longer shot at recovery. Some of the variables in people's lives are immune to good intentions or society's intervention; individuals choose how they want to live, and sometimes how they want to die.

But some are not immune. Equal access to treatment and tests. Expansion of affordable housing. An increase in substance abuse programs. More social workers. All of these things would signal this society's commitment to equal opportunity to life.

To grasp why these things matter, it helps to visit the Health Care for the Homeless Day Center. The men there unspool life stories seemingly sliced from the same film: Born into unforgiving, or unloving, circumstances, they devoted



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their lives to self-obliteration through drugs and alcohol. An HIV diagnosis triggered denial, but then, a desire for redemption and revival. It's as if once these men knew they might lose their lives, they began, for the first time, to believe they deserved them. One man tells me of starting on drugs at age six -- following in his mother's footsteps -- and then descending into homelessness, of days chasing a fix and nights sleeping in a '68 Volvo. When I meet him, he is HIV positive -- and handsome and fit, clothed smartly in jeans, a fitted T-shirt, a beret. "I smell good," he says. "I've got my complexion back. I've got shoes on my feet for the first time in six years."

Most of the men there aren't on protease inhibitors -- for reasons both financial and circumstantial -- but Benjamin Norris is. He incarnates the ideal: One eye wanders, one tooth is missing, but otherwise, he looks healthier than the doctor sitting next to him. The pills he takes daily, religiously, have multiplied his T-cells, restored his weight, boosted his optimism. This once homeless man has settled into an apartment; at age 50, he's hatching life plans. "I might be old one day," he beams -- although, wagging an elegantly manicured finger, he sternly reminds me that he isn't old yet.

Amy Waldman is an Outlook editor.

GRAPHIC: PAYING FOR AIDS CARE MEDICAID Provides care to at least 53 percent of adults and more than 90 percent of children with AIDS. In FY 1997, federal Medicaid costs for people with AIDS are estimated to be \$1.8 billion, with approximately 104,000 people with HIV and AIDS receiving benefits. AIDS DRUG ASSISTANCE PROGRAMS Monthly ADAP expenditures increased by 32 percent during the second half of 1996 with the introduction of protease inhibitors. Thirty-four ADAPs reported implementing some kind of emergency measures to cut costs during fiscal year 1996, including stopping enrollment or limiting access to protease inhibitors. In the region, Both Virginia's and Maryland's ADAP programs are open to anyone who meets their income criteria. Protease inhibitors are available through both programs. Virginia ADAP is currently serving 1,507 people; of those 497 are on protease inhibitors. Maryland ADAP has 700 patients enrolled; 50 to 70 percent of those are on protease inhibitors. SOURCE: AIDS Action Council, Maryland and Virginia ADAPs

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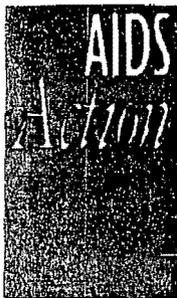
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FY 1996 HOPWA Formula Allocations

The FY 1996 appropriation of \$171 million provided \$153.9 million for formula allocations to 76 grants, including 49 Eligible Metropolitan Statistical Areas (EMSAs) and 27 States. The eleven first-time recipients are noted by *; the service area of six prior State grantees is reduced due to these new EMSAs. The applicant is the State or, for the EMSA, the most populous city in that area, which is the first jurisdiction named in the EMSA title (except as noted). The allocations are part of the area's consolidated plan.

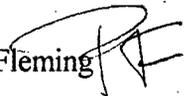
1996 Formula Grantee	Allocation (in 000s)	Grant Number
New England Region		
Connecticut (outside of the Hartford and New Haven EMSAs)	620	CT26H96-F001
Hartford CT MSA	535	CT26H96-F002
New Haven-Meriden CT FMSA *	403	CT26H96-F003
Massachusetts (outside the Boston EMSA)	898	MA06H96-F004
Boston MA-NH FMSA	1,613	MA06H96-F005
New York, New Jersey Region		
New Jersey (outside of 6 EMSAs)	617	NJ39H96-F006
Paterson for Bergen-Passaic NJ FMSA	1,044	NJ39H96-F007
Jersey City NJ FMSA	2,378	NJ39H96-F008
Woodbridge for the Middlesex-Somerset-Hunterdon NJ FMSA	556	NJ39H96-F009
Dover Township for the Monmouth-Ocean NJ FMSA *	473	NJ39H96-F010
Newark NJ FMSA	4,718	NJ39H96-F011
New York State (outside the New York City and Nassau FMSAs)	1,979	NY36H96-F012
Islip for the Nassau-Suffolk NY FMSA	1,043	NY36H96-F013
New York NY FMSA	35,840	NY36H96-F014
Mid-Atlantic Region		
Pennsylvania (outside the Philadelphia and Pittsburgh EMSAs)	793	PA26H96-F015
Philadelphia PA-NJ FMSA	2,682	PA26H96-F016
Pittsburgh PA MSA *	460	PA26H96-F017
Virginia (outside of DC and Norfolk EMSAs)	679	VA36H96-F018
Virginia Beach for the Norfolk-Virginia Beach-Newport News VA-NC MSA *	416	VA36H96-F019
Baltimore MD FMSA	4,582	MD06H96-F020
Washington DC-MD-VA-WV FMSA	5,026	DC39H96-F021

THE WHITE HOUSE

WASHINGTON

JUL 1 - 1996

MEMORANDUM FOR NANCY ANN MIN

FROM: Patsy Fleming 

SUBJECT: National Strategy for HIV and AIDS

The National Strategy for HIV and AIDS is in its final stages of review. Attached are the text and the appendices, including budget tables. The appendices are not complete pending the receipt of final comments from several departments and agencies. However, we wanted you to have as much opportunity as possible to review the text and begin reviewing the appendices. We will send the remaining department and agency information as soon as we have it, probably the beginning of next week.

The base set of budget figures in Appendix G are broken down in three different ways:

- (1) Overall HIV-related expenditures by Department and Agency;
- (2) HIV-related expenditures for Departments and Agencies by Area and Goal (only for those Departments and Agencies where HIV activities are not classified as part of the overall operating budget); and
- (3) HIV-related expenditures by area (i.e. prevention, research, care and services, etc)

The timeline for completion is as follows:

July 1	Draft to OMB for review
July 15	Final editing
July 22	Final draft sent for copying
August 8	Release date

We will brief the media, the AIDS organizations and key Congressional staff around the release date.

If you have any questions or comments please do not hesitate to call.

Attachments

cc: Richard Turman

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NATIONAL
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RESPONDING
TO
AIDS

AIDS APPROPRIATIONS
RECOMMENDATIONS
FISCAL YEAR 1997

A Coalition Convened by AIDS Action Council
1875 Connecticut Ave. NW, Suite 700, Washington, DC 20009
202-986-1300

Treatment Access Workgroup

Agenda

July 15, 1998

Introductions

Purpose of Workgroup – Sandra Thurman

Review of Information Provided – Todd Summers

Perspective of the Secretary of HHS – Marsha Martin

Work to Date

Health Care Financing Administration – Nancy-Ann Minn DeParle
Health Care Resources Services Administration – Joseph O'Neill

Analysis of Options – Sandra Thurman and Dan Mendelson

Next Steps

List of Participants

David Beier (Office of the VP)
Nancy-Ann Minn DeParle (HCFA)
Earl Fox (cannot attend) (HRSA)
Eric Goosby (cannot attend) (HHS/OS)
Chris Jennings (White House)
Marsha Martin (HHS/OS)
Dan Mendelson (OMB)
Joseph O'Neill (HRSA)
Sandra Thurman (ONAP)

Gordon Agress (OMB)
Sarah Bianchi (White House)
Toby Donenfeld (Office of the VP)
Robin Funston (HHS/ASMB)
Kathy King (HRSA)
John Palenicek (HRSA)
Todd Summers (ONAP)
Richard Turman (OMB)
Deborah vonZinkernagel (HHS/OS)
Greg White (OMB)

Treatment Access Workgroup

Issues Brief from OMB

July 15, 1998

Better Coordination Between Ryan White and Medicaid

Problem: The HHS Inspector General has recently pointed out that Medicaid managed care organizations and Ryan White programs do not adequately coordinate the services they provide to persons with HIV/AIDS.

Solution: The IG recommended that HCFA and HRSA disseminate technical assistance and guidance on strategies Medicaid programs can use to establish appropriate managed care contracts for needed medical services and costs related to these services. HRSA and 14CFA have begun to meet on these issues. The agencies could provide states with model contract language requiring coordination between Ryan White and Medicaid providers.

Discussion: Although Ryan White providers and Medicaid MCOs often serve the same population, they often do not coordinate services. For instance, the medical providers are often not aware of the Ryan White services, such as nutrition counseling and supplements, psycho-social services, home attendant care and case management, that the person is also getting. These social services, however, can help to support clients' ability to access health care and comply with health maintenance routines. Better coordination could result in better drug compliance and higher quality health care.

Higher Quality of HIV/AIDS Care in Medicaid

Problem: A recent study by the Agency for Health Care Policy and Research (AHCPR) has found that HIV+ persons with Medicaid received significantly inferior health care compared to privately insured persons. African-Americans, Latinos and women also received inferior care compared to whites and men.

Solution: Medicaid providers should be providing care based on the HHS guidelines on combination therapy that were released last year. HCFA and the States should ensure through contracting with managed care organizations or through direct contact with providers that all providers who serve the HIV+ population are aware of and adhere to the guidelines. Providing more services to HIV+ Medicaid recipients could impact the Medicaid baseline,

Discussion: At a time when it is possible to diminish radically the mortality and morbidity associated with HIV, this study suggests that Medicaid is not providing as high quality care to the HIV+ population as the insured population receives, even taking into account CD+4 lymphocyte counts. For instance, while only 13% of privately insured persons had one or more emergency room visits without an associated hospitalization, almost one third of Medicaid recipients had such an ER visit. Likewise, while 28% of privately insurance patients did not

receive protease inhibitors, almost one half of Medicaid beneficiaries did not. Differences in outcomes and quality between Medicaid recipients and private insured persons may occur between HIV-negative persons as well.

HCFA currently estimates that there are 50,000 asymptomatic persons who know their status plus 41,000 persons who are asymptomatic and do not know their status on Medicaid. Most of these people would be women eligible through the AFDC/TANF program. Providers should be encouraging all at-risk women to be tested for HIV.

Consumer Bill of Rights Could Improve Care for HIV+ Persons

Problem: Although privately insured HIV+ persons had the best health care access indicators in the AHCPH study, many privately insured persons are still not receiving adequate care. From the study, it is unclear whether the lack of adequate care is related to limited insurance coverage for appropriate care or poor provision of care by health providers.

Solution: Just as government employees in the Federal Employees Health Benefits program (FEHBP) have a guarantee to high quality care through the adoption of the Consumer Bill of Rights, all private employees and members of health plans should have a guarantee of high quality care consistent with the Consumer Bill of Rights.

Discussion: The President's Consumer Bill of Rights calls for improvements in the quality of managed care that would enhance care for persons with HIV. For instance, the Consumer Bill of Rights requires that consumers with complex or serious medical conditions have direct access to qualified specialists. Consumers who are undergoing treatment for a chronic condition, such as AIDS, at the time they involuntarily change health plans or when a provider is terminated by a plan should be able to continue to see their original specialty provider for up to 90 days. Consumers should have the right to considerate, respectful care and should not be discriminated against based on race, ethnicity, national origin, religion, sex, age, mental or physical disability, sexual orientation, genetic information or source of payment.

Reductions in AIDS Deaths Vary by Race and Gender

Problem: AIDS death rates for women and African-Americans have not fallen as dramatically as have AIDS death rates for men and for whites -- possibly because women and African-Americans may not be receiving the same quality and/or amount of care as men and whites.

Possible Solutions: Exactly what improvements would be most efficient is not yet clear from the data, but there are some potential starting points.

- Address the inexperience of many physicians by better disseminating HHS clinical practice guidelines, or by referring patients to more experienced doctors.
- Imposition of some "quality of care" standard among Ryan White grantees.
- Use Ryan White's AIDS Education and Training Center component to identify and address gaps in physicians' knowledge of care for I-HIV/AIDS.
- Increase awareness in community of benefits from early intervention.

Data: CDC AIDS data show that death rates have not fallen as dramatically among women and blacks as they have among whites and men.

Merck data show that "women and minorities are more likely to be HIV symptomatic than white men when starting HIV treatment," and "a smaller proportion of women and minorities than white men are treated by the most experienced physicians."

Access to Combination Therapy May Vary By State

Problem: Some Southern and Western states tend to have waiting lists for ADAP and/or combination therapy.

Possible Solutions: If the access problems in these States are driven by resource levels, then finding more resources -- either from individuals, companies, the State or local governments or the Federal government -- is probably the only way to address the problems.

We could seek to increase the contributions made by the States. States with AIDS cases greater than 1% of the national total* are currently required to provide State resources equal to 50% of the Title 11 grants (which include ADAP), but States can meet this requirement with "in kind" contributions such as facilities and staff. States could be required to increase the match they make to ADAP grants, or could be required to make their matching contributions in cash. This has been discussed in the past, and would be fairly controversial, but it is worth thinking about.

Increased funding for Title 11 and ADAP would help, but because these funds are distributed by formula, increases to them are unlikely to have a large impact in the States with problems. We could increase funding for Title III, which makes grants directly to clinics, and target the funds to States with access problems. We could also propose changes to the Title 11 and ADAP formulas, but these are unlikely to occur quickly,

Discussion: Nationwide, States provided 30% of the funds used by ADAPs in FY 1997. States that AIDS Action lists as having waiting lists for combination therapy contributed 20% of ADAP funds in their State -- less than the national average for ADAP.

Insurance Continuation

Problem: States cannot use ADAP funds to pay premiums for clients' health insurance even when that health insurance would cover combination therapy, and the cost of the premiums is less than the cost of buying the drugs directly.

Solution: Let States use ADAP funds to pay for health insurance when the insurance is the cheapest way of providing access to combination therapy, and when clients cannot afford to pay for such insurance themselves. As in any other public insurance program, the public insurance may be substituting for private insurance that people would have purchased if the public insurance was not available -- a phenomenon known as "crowd-out." Policy could be proposed which would reduce the level of "crowd-out."

Discussion: The FY 1999 President's Budget included appropriations language signaling support for this idea, but this language has been viewed by the community as inadequate to give States the authority they need. The House Labor/HHS Appropriations Subcommittee report says States should have the flexibility to do insurance continuation.

Cost of Drugs

Problem: Ryan White grantees and Medicaid programs may be spending more than they have to for AIDS drugs.

Solution: Insure these activities use the minimum price available to them by making maximum use of HHS 340B program and Medicaid rebates and discounts.

Discussion: We do not have much evidence to suggest that significant savings are available through cost minimization efforts. However, given the high cost of combination therapy drugs, small percentage reductions in the prices paid for these drugs could result in large dollar savings. HHS is already publishing a rule that would allow States to use a rebate program to capture the savings from this program (now currently available only as a discount).

*CDC estimates that 242,000 people were living with AIDS in 1996, and that 641,000 total cases had been reported by the end of 1996. The law imposes the matching requirement on States whose AIDS cases are "in excess of 1 percent of the aggregate number of such cases" -- it is unclear whether this refers to living persons or all AIDS cases.

emergency medical services to acutely ill and seriously injured children.

Black Lung Clinics

The Committee provides \$5,000,000 for black lung clinics, which is \$24,000 above the fiscal year 1998 comparable level and the same as the Administration request. The program supports 14 grantees which treat a declining population of coal miners with respiratory and pulmonary impairments. The clinics presently receive more than one-third of their funding from other sources, such as Medicaid and Medicare. Of the 14 grantees, three actually receive community health center funding as well as black lung grants.

Payment to Hawaii for Treatment of Hansen's Disease

The Committee provides \$2,045,000 for the treatment of persons with Hansen's Disease in the State of Hawaii, which is the same as both the fiscal year 1998 comparable level and the Administration request. The program, which provides a partial matching payment to the State of Hawaii, dates to the period of Father Damien's facility for sufferers of Hansen's disease (leprosy). That facility now has only 67 residents who live there by choice, and the grounds have been converted to a historical site. Most patients diagnosed with Hansen's disease in Hawaii are now treated in the same manner as new patients on the mainland; their care is handled on an out-patient basis, with the program paying for about 5,300 out-patient visits per year.

Ryan White AIDS Programs

The Committee provides \$1,330,600,000 for Ryan White AIDS programs, which is \$181,088,000 above the fiscal year 1998 comparable level and \$17,618,000 above the Administration request. The Committee recognizes that each Part of the Ryan White CARE Act provides services, which enable individuals to adhere to HIV drug treatments and access needed medical care.

The Ryan White CARE Act Amendments of 1996 requires States to comply with certain requirements in order to receive Federal funding for Ryan White activities. There is some concern that the Department is certifying States as being in compliance with these requirements when, in fact, they are not. Therefore, the Committee requests that the Secretary submit, by October 15, 1998, the following information: (1) a copy of the guidelines that were provided to State's to comply with section 300ff-21 et. seq. and section 300ff-47 of the Act; (2) a copy of the criteria used by the Department to evaluate and certify a State's compliance with these sections; (3) a copy of what each State submitted to the Department for its compliance evaluation; and (4) a copy of each State's final evaluation and certification approval document by the Department.

Emergency assistance

The Committee provides \$500,200,000 for the Part A, emergency assistance program, which is \$35,464,000 above the fiscal year 1998 comparable level and \$11,226,000 above the Administration request. These funds provide grants to metropolitan areas with very high numbers of AIDS cases for outpatient and ambulatory

health and social support services. Half of the amount appropriated is allocated by formula and half is allocated to eligible areas demonstrating additional need through a competitive grant process.

Comprehensive care programs

The Committee provides \$670,000,000 for Part B, comprehensive care programs, which is \$127,217,000 above the fiscal year 1998 comparable level and \$1,130,000 above the Administration request. The funds provided support formula grants to States for the operation of HIV service delivery consortia in the localities most heavily affected, for the provision of home and community-based care, for continuation of health insurance coverage for infected persons, and for purchase of therapeutic drugs.

The Committee is encouraged by the success of new drugs and combination therapies for HIV and AIDS, whose purchase is principally financed under Part B, and has included bill language identifying \$385,500,000 specifically for the purchase of AIDS drugs. The fiscal year 1998 bill designated \$285,500,000 for this purpose.

The Committee is concerned about the wide variation in State ADAP and Medicaid policies regarding eligibility, benefits, and formularies. The Committee is also concerned about the wide variation in State contributions to funding of ADAP and urges States that receive more than \$1,000,000 under the targeted formula to match no less than twenty percent of the Federal contribution. The Committee directs the program to use all means necessary to reduce the purchase price of AIDS drugs.

The Committee expects HRSA to encourage States to utilize Federal ADAP funding in the most cost effective manner possible to maximize access to and use of HIV drug therapies. States should be allowed, with ADAP funding, the flexibility to purchase and maintain insurance policies for eligible clients, or continue to pay premiums on existing insurance policies, which provide a full range of HIV treatments and access to comprehensive primary care services as determined by the State. Funds should not be used to purchase insurance which provides inadequate access to HIV treatments or primary care as determined by the State.

Early intervention program

The Committee provides \$91,300,000 for Part C, the early intervention program, which is \$15,089,000 above the fiscal year 1998 comparable level and \$5,146,000 above the Administration request. Funds are used for discretionary grants to migrant and community health centers, health care for the homeless grantees, family planning grantees, hemophilia centers and other private non-profit entities that provide comprehensive primary care services to populations with or at risk for HIV disease. The grantees provide testing, risk reduction counseling, transmission prevention, and clinical care; case management, outreach, and eligibility assistance are optional services. Approximately 79,000 HIV positive persons or persons at high risk for HIV infection are expected to be served in fiscal year 1999.

The Committee is concerned about the continued disparity in health outcomes for people with HIV and AIDS in communities of color and recognizes the need to provide additional services specifi-

cally targeted to HIV infected individuals in these communities. The Committee encourages HRSA to give priority consideration to allocating grants to grantees serving primarily minority populations.

Pediatric demonstrations

The Committee provides \$44,000,000 for Part D, the pediatric AIDS demonstrations, which is \$3,197,000 above the fiscal year 1998 comparable level and \$74,000 above the Administration request. The program supports demonstration grants to foster collaboration between clinical research institutions and primary community-based medical and social service providers for the target population of HIV-infected children, pregnant women and their families. The projects are intended to increase access to comprehensive care, as well as to voluntary participation in NIH and other clinical trials.

AIDS dental services

The Committee provides \$7,800,000 for AIDS dental services, which is \$37,000 above the fiscal year 1998 comparable level and \$13,000 above the Administration request. The program provides grants to dental schools and postdoctoral dental education programs to assist with the cost of providing unreimbursed oral health care to an estimated 73,000 patients with human immunodeficiency virus disease. Over one hundred dental schools and hospitals are expected to receive awards in fiscal year 1999. Dental students and residents participating in this program receive extensive training in the management of oral care of people living with AIDS.

The Committee notes that the program funding formula and reporting requirements have been revised in fiscal year 1998, and therefore, requests that the agency provide adequate time and technical assistance so that grantees can comply with these revisions and any future program changes allowing for their continued participation in the program.

Education and training centers

The Committee provides \$17,300,000 for AIDS education and training centers, which is \$84,000 above the fiscal year 1998 comparable level and \$29,000 above the Administration request. The centers train health care personnel who care for AIDS patients and develop model education programs.

Family Planning

The Committee provides \$202,903,000 for the family planning program, which is the same as the fiscal year 1998 comparable level and \$15,174,000 below the Administration request. The program provides grants to public and private non-profit agencies to support projects which provide a range of family planning and reproductive services, as well as screening for ancillary health problems such as hypertension and diabetes. The program also supports training for providers, an information and education program, and a research program which focuses on family planning service deliv-

ery improvements. During fiscal year 1999, an estimated 4.6 million clients are expected to be served.

The bill repeats language from the 1998 appropriations bill making clear that these funds shall not be expended for abortions, that all pregnancy counseling shall be nondirective, and that these funds shall not be used to promote public opposition to or support of any legislative proposal or candidate for public office.

Rural Health Research

The Committee provides \$7,500,000 for rural health research, which is \$4,156,000 below the fiscal year 1998 comparable level and \$4,191,000 below the Administration request. The activity supports several rural health research centers and the Office for Rural Health Policy's advisory committee.

Health Care Facilities

The Committee has not included funding for health care facilities. \$28,000,000 was provided for this purpose in fiscal year 1998; no funding was included in the Administration request. This expired authority provides funds to public and private nonprofit entities for construction or modernization of outpatient medical facilities. This activity has not been funded by the Committee on a regular annual basis.

Buildings and Facilities

The Committee provides \$250,000 for buildings and facilities, which is \$2,248,000 below the fiscal year 1998 comparable level and the same as the Administration request. These funds are used to finance the repair and upkeep of buildings at the Gillis W. Long Hansen's Disease Center at Carville, Louisiana.

National Practitioner Data Bank

The Committee does not provide funding for the national practitioner data bank for fiscal year 1999, which is the same as both the fiscal year 1998 action on appropriations and the Administration request. The Committee recommendation and the Administration request assume that the data bank will be self-supporting, with collections of \$12,000,000 in user fees.

The national data bank receives, stores and disseminates information on paid medical malpractice judgments and settlements, sanctions taken by professional societies, and certain professional review actions. Insurance companies, State license boards and professional societies are required to report information to the data bank within 30 days of each action. The coverage of the data bank includes dentists and physicians, and, with respect to malpractice settlements, other categories of licensed health professionals. Hospitals are required to search the data bank when a health care provider applies for employment and once every two years thereafter. State licensing boards and other health care entities also have access to the data bank. Traditional bill language is included to ensure that user fees are collected to cover all costs of processing requests and providing such information to data bank users.

disease, kidney disease, and other health problems that disproportionately afflict the elderly. Last year the Committee encouraged HCFA to conduct a demonstration project on coverage of medical nutrition therapy by registered dietitians and other licensed or nationally certified medical practitioners under Part B of Medicare to investigate its impact on program costs and beneficiary health and quality of life. The Committee is concerned that no progress has been made on this demonstration and urges HCFA to proceed with this project and provide a report on its status by December 31, 1998.

The Committee notes that congestive heart failure (CHF) has been identified as the leading condition regarding readmission, with the majority of those readmissions occurring through emergency rooms. This problem is particularly acute in the "stroke belt" region, which encompasses several Southern and Midwestern states. The Committee encourages HCFA to undertake research to demonstrate the cost effectiveness of a CHF clinic in reducing hospital admissions and improving compliance and quality of life.

Treatment guidelines issued by the Department in 1997 recognize the need to provide early treatment for HIV disease. Several States are considering applications for Medicaid waivers for demonstration projects that would extend Medicaid eligibility to HIV positive individuals who meet State Medicaid income eligibility requirements, but are not diagnosed with AIDS. The Committee encourages HCFA to evaluate and provide technical assistance to states which are preparing waiver applications for these demonstration projects.

Recent evidence from the states indicates that many Medicaid recipients with the most severe and disabling mental illnesses can achieve higher levels of recovery if the appropriate treatment and supports are available in the community. While a model of intensive case management known as the Program for Assertive Community Treatment (PACT) has been successful as part of Medicaid programs in many states, there is little information about how many states are funding PACT services. The Committee encourages HCFA to undertake a survey of which states are funding PACT services for adult Medicaid beneficiaries with severe mental illnesses and develop a model on how states can successfully integrate PACT into managed care programs.

The Committee supports the efforts to reach underserved and vulnerable populations through telemedicine and expects that projects will be supported in both rural and urban communities to meet the health care needs of underserved and minority populations.

Medicare contractors

The bill includes \$1,269,700,000 to support Medicare claims processing contracts, which is \$53,559,000 above the fiscal year 1998 comparable level and \$165,300,000 above the Administration request. The Committee does not concur with the Administration's new user fee proposal.

Medicare contractors are responsible for paying Medicare providers promptly and accurately. In addition to processing claims, contractors also identify and recover Medicare overpayments, as well

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Early Access to HIV Treatments for Underserved Populations Found to be Cost Effective

- AIDS Activists Applaud New Research That Puts Added Pressure on Government Officials to Expand Treatment Access -

GENEVA, July 2 /PRNewswire/ -- New pharmacoeconomic research presented today at the 12th World AIDS Conference demonstrates that providing early access to AIDS treatment for the poor and uninsured would be cost-effective. This study challenges underlying assumptions supporting current Medicaid requirements that withhold treatment from HIV-infected patients until they exhibit the symptoms of full-blown AIDS. Medicaid is the largest payer of HIV-related medical services in the United States.

Current Medicaid eligibility rules extend health care coverage to HIV-infected patients only after they have suffered an AIDS defining illness or after their CD4 count has declined to below 200. Patients living with the HIV virus but without the symptoms of full-blown AIDS are ineligible and, if unable to gain access to AIDS drugs through other means, must delay treatment until they experience the symptoms of AIDS. Although federally funded state-administered AIDS Drug

Assistance Programs (ADAPs) generally cover the drug costs for patients ineligible for Medicaid, many state programs have experienced financial shortfalls due to rapidly increasing enrollments and per patient costs and, as a result, have responded by restricting access to their programs.

AIDS activists attending the conference characterized the pharmacoeconomic study as a solid first step in the development of a critical policy basis for the expansion of life-saving AIDS drug therapies to the uninsured and underinsured. The research, which was conducted by a consortium of academic researchers, professional pharmacoeconomists, AIDS organizations and research-based pharmaceutical interests called the Treatment Access Expansion Project (TAEP), uses established pharmacoeconomic simulation techniques and data from existing clinical trials (Roche clinical trials NV15182 and NV15355) to draw two conclusions:

-- early initiation of treatment with AIDS drug cocktails delays the progression of AIDS, and

-- providing early treatment (i.e., when the patient has a CD4 count between 200 and 500 and has never experienced an AIDS defining event)

would result in prolonged survival and would be cost-effective, when compared to delayed treatment (when the patient has a CD4 count of less than 200 or has experienced an AIDS defining event).

"At the most basic level, our research shows that patients receiving early, aggressive treatment experience increased lifespan," said Gary Rose, T.I.C.A.N.N. (Ryan White CARE Act Title II Community AIDS National Network) public policy director and community liaison with the Treatment Access Expansion Project and a chief researcher on the project. "Moreover, the overall cost of providing patients with this survival benefit is negligible."

In April 1997, Vice President Al Gore directed federal health officials to determine the feasibility of expanding Medicaid coverage to make new AIDS drugs available to the uninsured for early HIV treatment. In December, the Clinton Administration announced that an expansion in Medicaid along these lines would be too costly. "Ability to pay should not have to be a barrier to early intervention for people with HIV," said Daniel Zingale, Executive Director of the AIDS Action Council.

The new pharmacoeconomic study shows that early HIV treatment would increase life expectancy of currently infected asymptomatic patients (patients with a CD4 count between 200-500 and never having experienced an AIDS defining event) by 0.43 years (unadjusted for quality of life). The researchers determined that these gains in life expectancy would result in longer treatment with protease inhibitors and an expected increase in lifetime costs per patient of 2.2%. Ultimately, however, early AIDS treatment is projected to delay progression of AIDS-defining events and prolong survival, at a cost well within the range of generally accepted cost-effective medical interventions.

"This pharmacoeconomic study provides an important addition to any discussion on early treatment," said Dr. John Hornberger, Director of Health Economics in Roche Global Pharmacoeconomic Research. "By delaying the onset of the symptoms of AIDS, early treatment only slightly increases medical-care costs over the first 5 years by \$241 per patient per year."

The principal sponsor of the TAEP pharmacoeconomic study is Hoffmann-La Roche. Roche Laboratories, a subsidiary of Hoffmann-La Roche, markets more than 35 medications in major therapeutic areas including AIDS, oncology, transplantation, infectious diseases, cardiovascular diseases and dermatology.

Treatment Access Expansion Project: TAEP was initiated to develop and disseminate sophisticated pharmacoeconomic models for use by federal, state and local governments and other entities concerned with the budget

implications of providing treatment to people living with HIV/AIDS. TAEP consists of a consortium of academic researchers, professional pharmacoeconomists, AIDS organizations and research-based pharmaceutical interests.

T.I.C.A.N.N.: The Ryan White CARE Act Title II Community AIDS National Network (T.I.C.A.N.N.) is a non-profit organization dedicated to initiating and supporting activities that ensure access to care for all Americans living with or affected by HIV.

Roche Laboratories Inc.: Roche Laboratories Inc. is the marketing and sales subsidiary of Hoffmann-La Roche Inc., a leading research-intensive pharmaceutical company. Roche Laboratories markets more than 35 medications in major therapeutic areas including AIDS, oncology, transplantation, infectious diseases, cardiovascular diseases and dermatology.

SOURCE Treatment Access Expansion Project

CO: Treatment Access Expansion Project; Roche Laboratories Inc.; T.I.C.A.N.N.