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Agency Reviews-June 1996 [2]

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THE WHITE HOUSE

WASHINGTON

June 12, 1996

MEMORANDUM FOR THE INTERDEPARTMENTAL TASK FORCE ON HIV AND AIDS,  
DEPARTMENT OF HEALTH AND HUMAN SERVICES

FROM:

Patricia S. Fleming

Director, Office of National AIDS Policy

SUBJECT: Review of Draft of the National Strategy for HIV and AIDS

Attached is the revised draft of the National Strategy for HIV and AIDS. The comments DHHS provided have been considered and incorporated to the extent possible. If you have further comments, the new suggested language must be specific.

Please review the budget table on the follow pages to this memo carefully. You should:

- Update the budget table to reflect current figures, noting FY 95 actuals, FY 96 estimates, and the FY 97 President's budget request for each agency goal. (These budget figures will be cross-checked with OMB figures and the Federal Biomedical and Behavioral Research Plan and Budget for HIV and AIDS, April 1996.) The attached table reflects the budget levels provided in your revised submission.

Comments are due back to the Office of National AIDS Policy **BY NO LATER THAN JUNE 19, 1996**. If you have any questions please call Jane Sanville at (202) 632-1090.

Thank you for your assistance in developing this first-ever National Strategy for HIV and AIDS.

Attachments: Summary Budget Tables

The National Strategy for HIV and AIDS, 6.11.96 draft

DHHS Appendices for The National Strategy for HIV and AIDS, 6.11.96 draft

**PAGE 2: MEMORANDUM FOR THE INTERDEPARTMENTAL TASK FORCE ON  
HIV AND AIDS, DEPARTMENT OF HEALTH AND HUMAN SERVICES**

| AGENCY | GOALS                                                                                                                                                                                                            | FY 95<br>Actuals | FY 96 | FY 97<br>President's<br>Budget |
|--------|------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|------------------|-------|--------------------------------|
| NIH    | Natural History and<br>Epidemiology<br><br>Etiology and<br>Pathogenesis<br><br>Therapeutics<br><br>Vaccines<br><br>Behavioral Research<br><br>Training and<br>Infrastructure<br><br>Information<br>Dissemination |                  |       |                                |

|     |                                                                                                                                                                                                          |               |               |  |
|-----|----------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|---------------|---------------|--|
| CDC | More accurately monitor the HIV epidemic and provide data to assess and direct prevention programs by strengthening existing systems and develop new surveillance systems.                               | \$141,076,000 | \$140,917,000 |  |
|     | Increase the public understanding of, involvement in, and support for HIV prevention                                                                                                                     | \$45,970,000  | \$46,869,000  |  |
|     | Prevent risk behaviors that can cause HIV infection and related health problems in school age children and college age persons through implementation of comprehensive school health education programs. | \$48,215,000  | \$48,162,000  |  |
|     | Prevent or reduce behaviors or practices which place individuals at risk of HIV infection, and for HIV positive individuals, place others at risk.                                                       | \$185,666,000 | \$209,764,000 |  |
|     | Increase individual knowledge of sero-status and strengthen systems for successful referral to early intervention services.                                                                              | \$169,035,000 | \$179,006,000 |  |

|      |                                                                                                  |                                                                                         |                                                                                         |  |
|------|--------------------------------------------------------------------------------------------------|-----------------------------------------------------------------------------------------|-----------------------------------------------------------------------------------------|--|
| HRSA | Increase the number of competent primary care providers willing to care for HIV positive persons | \$16,300,000                                                                            | \$16,300,000                                                                            |  |
|      | Reduce barriers to obtaining dental care for HIV positive persons                                | \$6,937,000                                                                             | \$6,937,000                                                                             |  |
|      | Increase access to care and improve quality of life for persons living with HIV/AIDS             | \$632,965,000<br>I: 356,500,000<br>II: 198,147,000<br>III: 52,318,000<br>IV: 26,000,000 | \$723,465,000<br>I: 407,000,000<br>II: 221,897,000<br>III: 62,568,000<br>IV: 32,000,000 |  |
|      | Develop and evaluate innovative models of comprehensive managed care for persons living with HIV | Objective 1:<br>\$2,092,302<br><br>Objective 2:<br>\$4,000,00                           | Objective 1:<br>\$4,000,00<br><br>Objective 2:<br>\$4,000,00                            |  |
|      | Reduce the perinatal transmission of HIV                                                         | \$1,520,000                                                                             | \$1,800,000                                                                             |  |

|        |                                                                                                   |                                                                                 |                                                                                 |  |
|--------|---------------------------------------------------------------------------------------------------|---------------------------------------------------------------------------------|---------------------------------------------------------------------------------|--|
| SAMHSA | Reduce the rate of HIV transmission among high-risk substance abusers and their sexual partners   | Objective 1:<br>\$1,500,00<br>(With 1,500,000 from HRSA & \$1,400,000 from NIH) | Objective 1:<br>\$1,500,00<br>(With 1,500,000 from HRSA & \$1,400,000 from NIH) |  |
|        |                                                                                                   | Objective 2:<br>\$7,500,000                                                     | Objective 2:<br>\$7,500,000                                                     |  |
|        | Improve HIV/AIDS training of clinicians                                                           | Objective 1:<br>\$2,930,000                                                     | Objective 1:<br>\$2,800,000                                                     |  |
|        |                                                                                                   | Objective 2:<br>\$2,800,00                                                      | Objective 2:<br>\$0                                                             |  |
|        | Improve the integration of substance treatment and primary medical care                           | \$7,700,000                                                                     |                                                                                 |  |
| AHCPR  | Reduce the number of new HIV infections                                                           | Objective 1:<br>\$1,000,000                                                     | Objective 1:<br>\$3,000,000                                                     |  |
|        |                                                                                                   | Objective 2:<br>\$0                                                             | Objective 2:<br>\$5,000,000                                                     |  |
|        |                                                                                                   | Objective 3:<br>\$                                                              | Objective 3:<br>\$                                                              |  |
|        | To provide national estimates of the cost and use of HIV-related medical and non-medical services | \$6,744,480                                                                     | \$5,015,707                                                                     |  |
|        | To provide national estimates of the cost and use of HIV-related prevention services              | \$1,051,075                                                                     | \$56,308                                                                        |  |
| IHS    | To expedite the dissemination of data from research                                               | \$318,833                                                                       | \$155,000                                                                       |  |
|        | Reduce the number of infections among Federally recognized American Indians and Alaska Natives    | Objective 1:<br>\$912,000                                                       | Objective 1:<br>\$912,000                                                       |  |
|        |                                                                                                   | Objective 2:<br>\$2,321,000                                                     | Objective 2:<br>\$2,321,000                                                     |  |

|     |                                                                                                                                                        |                                                  |                                                  |  |
|-----|--------------------------------------------------------------------------------------------------------------------------------------------------------|--------------------------------------------------|--------------------------------------------------|--|
| FDA | Ensure the safety and effectiveness of HIV-related therapeutic agents                                                                                  | \$25,235,000                                     | \$25,536,000                                     |  |
|     | Ensure the safety and effectiveness of HIV-related preventive and therapeutic vaccines                                                                 | \$11,863,000                                     | \$12,005,000                                     |  |
|     | Ensure the effectiveness of test methodologies (such as diagnostic reagents and test kits) for HIV detection, confirmation, and viral load measurement | \$8,732,000                                      | \$8,836,000                                      |  |
|     | Reduce transfusion-transmitted HIV infection                                                                                                           | \$17,458,000                                     | \$17,667,000                                     |  |
|     | Ensure the safety and effectiveness of HIV-related medical devices                                                                                     | \$9,457,000                                      | \$9,570,000                                      |  |
| ACF | To meet the social and support service needs of children, youth, and families with or at risk for HIV/AIDS                                             | NA - HIV services integrated into overall budget | NA - HIV services integrated into overall budget |  |
| OPA | Reduce the number of new infections                                                                                                                    | NA - HIV services integrated into overall budget | NA - HIV services integrated into overall budget |  |

|      |                                                                                                                                                                                                                                                                         |                 |                 |  |
|------|-------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|-----------------|-----------------|--|
| HCFA | Reduce perinatal transmission among Medicaid-eligible women                                                                                                                                                                                                             | \$50,000        |                 |  |
|      | Provide quality home health care for HIV positive Medicaid and Medicare beneficiaries                                                                                                                                                                                   | \$25,000        |                 |  |
|      | Provide primary health care to Medicaid-eligible HIV-positive persons                                                                                                                                                                                                   | \$1,640,000,000 | \$1,800,000,000 |  |
| OIH  | Support US interests globally by serving as a policy and coordinating body for international activities supported by HHS, a liaison with other US departments and agencies supporting international activities, and a liaison with foreign governments working with US. | NA              | NA              |  |

***III. APPENDICES***

***DHHS Appendices:***

The Administration for Children and Families (ACF)  
The Agency for Health Care Policy and Research (AHCPR)  
The Centers for Disease Control and Prevention (CDC)  
The Food and Drug Administration (FDA)  
The Health Care Financing Administration (HCFA)  
The Health Resources and Services Administration (HRSA)  
The Indian Health Service (IHS)  
The National Institutes of Health (NIH)  
The Office of International Affairs (OIA)  
The Office of Population Affairs (OPA)  
The Substance Abuse and Mental Health Services Administration (SAMSHA)

## **CARE AND SERVICES**

**Agency:** Administration for Children and Families

**Goal:** To meet the social and support service needs of children, youth, and families with or at risk for HIV/AIDS.

**Objective 1:** Stabilize the crisis situation and provide needed services to runaway and homeless youth.

**Action Steps:** Provide shelter and immediate services including diagnostic medical services and education and prevention related to HIV/AIDS.

**Descriptions:** Runaway and Homeless Youth Program.

**FY 95:** NA -- HIV services integrated into overall budget.

**FY 96:** NA -- HIV services integrated into overall budget.

**FY 97:**

**Populations Served:** Runaway and homeless youth at risk for HIV.

**Constituency Involvement:** A network of more than 500 grantees, both public and private.

**Unmet Need:** More services and resources need to be available, particularly in the areas of education and prevention.

**Objective 2:** Provide foster care and adoption services to abused, neglected, or otherwise needy children including those with HIV/AIDS.

**Action Steps:** Provide diagnostic and treatment services, counseling for children, parents, extended family, foster and adoptive parents, and others relevant to HIV/AIDS.

**Descriptions:** Child Welfare Services Program.

**FY 95:** NA -- HIV services integrated into overall budget.

**FY 96:** NA -- HIV services integrated into overall budget.

**FY 97:**

**Populations Served:** Children in foster care and those placed in adoption, their parents, and extended families.

**Constituency Involvement:** National, professional, advocacy, and service organizations such

***The National Strategy for HIV and AIDS -- ACF Appendix  
Draft for Department of Health and Human Services Review: 6.11.96***

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as the Child Welfare League of America, American Public Welfare Association, National Association of Social Workers, and 56 State/Territorial grantees.

**Unmet Need:** More services and resources need to be available.

**Objective 3:** Support health and social services for abandoned infants and young children who have been drug-exposed and/or have HIV/AIDS.

**Action Steps:** Provide foster care, health services, counseling and other social services.

**Descriptions:** Abandoned Infants Assistance Program.

**FY 95:** NA -- HIV services integrated into overall budget.

**FY 96:** NA -- HIV services integrated into overall budget.

**FY 97:**

**Populations Served:** Abandoned infants and young children who have been drug-exposed and/or have HIV/AIDS.

**Constituency Involvement:** Public and private providers of these services, grantees, and national resource agencies.

**Unmet Need:** Resources to serve geographic areas of unmet needs.

**Objective 4:** The Head Start Program provides comprehensive child development services to children, including those with HIV/AIDS, their parents, and families.

**Action Steps:** Services to Head Start families may include prevention and education, identification, and intervention related to HIV/AIDS; children with HIV/AIDS are enrolled in the on-going Head Start program.

**Descriptions:** Head Start Program.

**FY 95:** NA -- HIV services integrated into overall budget.

**FY 96:** NA -- HIV services integrated into overall budget.

**FY 97:**

**Populations Served:** Low income pre-schoolers and their families, including pregnant women.

***The National Strategy for HIV and AIDS -- ACF Appendix  
Draft for Department of Health and Human Services Review: 6.11.96***

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**Constituency Involvement:** National Head Start Association and related early childhood development organizations, such as National Association for the Education of Young Children.

**Unmet Need:** Increased resources will make services available to more children.

**Objective 5:** Support the independence, productivity, and integration into the community of persons with developmental disabilities.

**Action Steps:** Twenty-seven of the current 51 grantees operate Pediatric HIV/AIDS Clinics in or associated with the university.

**Descriptions:** University Affiliated Program

**FY 95:** NA -- HIV services integrated into overall budget.

**FY 96:** NA -- HIV services integrated into overall budget.

**FY 97:**

**Populations Served:** Developmentally disabled persons, including those with HIV/AIDS.

**Constituency Involvement:** National network of grantees; national advocacy organizations related to HIV/AIDS and developmental disabilities.

**Unmet Need:** Although a university pediatric AIDS clinic is located in each state, not all patients have access to the services.

## **RESEARCH**

**Agency:** Agency for Health Care Policy and Research

**Goal:** To provide national estimates of the cost and use of HIV-related medical and non-medical services.

**Objective 1:** To provide comprehensive information on unmet needs for service and barriers to accessing services.

To examine effects of different systems of organizing and delivering care on outcomes such as cost, utilization, survival, patient satisfaction, and quality of life.

To examine effects of patient characteristics (including gender, race/ethnicity, substance abuse, mental health, socioeconomic status, insurance coverage) on outcomes such as service utilization, unmet service needs, and costs.

To provide data on service utilization and costs for a representative sample of rural residents with HIV infection.

To examine patterns of transition between different types of provider (e.g., private physician to public clinic) and the relationship of such transitions to changes in clinical status, employment, and insurance coverage.

**Action Steps:** This study will be the first to obtain a true national random sample of people with HIV infection receiving treatment. Approximately 3200 adult patients in urban and rural areas will be enrolled. Study will be co-sponsored by HRSA, NIMH, NIDR, NIA, NIDA, and the Robert Wood Johnson Foundation.

**Descriptions:** HIV Costs and Service Utilization Study (HCSUS)

**FY 95:** \$4,000,000

**FY 96:** \$4,000,000

**FY 97:**

**Populations Served:** HIV-infected individuals receiving treatment.

**Constituency Involvement:** Community Advisory Board, comprising members of infected and affected groups, has been established.

***The National Strategy for HIV and AIDS -- AHCPR Appendix  
Draft for Department of Health and Human Services Review: 6.11.96***

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**Unmet Need:** Insufficient resources for a national probability sample of pediatric HIV-infected patients. Insufficient resources for a sample of HIV-infected adolescents.

**Objective 2:** To examine health care utilization among participants in the NIH-sponsored Women's Interagency HIV Study (WIHS).

**Action Steps:** Supplement the WIHS by adding a health services research component.

Collect and analyze utilization data on women with HIV infection (in addition to the detailed clinical data obtained in the core study.)

**Descriptions:** Women's Interagency HIV Study (WIHS)

**FY 95:** \$60,000

**FY 96:** \$0

**FY 97:**

**Populations Served:** Women with HIV infection participating in the WIHS.

**Constituency Involvement:** A broad representation of researchers and patient advocates had input in the development of the WIHS.

**Unmet Need:** None.

**Objective 3:** To examine factors affecting health care utilization among participants in the NIH-sponsored Multicenter AIDS Cohort Study (MACS).

**Action Steps:** Supplement the MACS by adding a health services research component.

Collect and analyze utilization data on men with HIV infection (in addition to the detailed clinical data obtained in the core study.)

**Descriptions:** Multicenter AIDS Cohort Study (MACS)

**FY 95:** \$65,000

**FY 96:** \$0

**FY 97:**

**Populations Served:** Homosexual and bisexual men participating in the MACS in four urban areas.

***The National Strategy for HIV and AIDS -- AHCPR Appendix  
Draft for Department of Health and Human Services Review: 6.11.96***

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**Constituency Involvement:** A broad representation of researchers and patient advocates had input in the development of the MACS.

**Unmet Need:** None

**Objective 4:** To examine health care utilization among participants in the CDC-sponsored HIV Epidemiological Research Study (HERS).

**Action Steps:** Supplement the HERS by adding a health services research component.

Collect and analyze utilization data on women with HIV infection (in addition to the detailed clinical data obtained in the core study.)

**Descriptions:** HIV Epidemiological Research Study (HERS)

**FY 95:** \$50,000

**FY 96:** \$50,000

**FY97:**

**Populations Served:** Women with HIV infection participating in the HERS.

**Constituency Involvement:** A broad representation of researchers and patient advocates had input in the development of the HERS.

**Unmet Need:** None.

**Objective 5:** To provide longitudinal data on utilization of inpatient, outpatient, home care, pharmaceutical, and other services, and to estimate their associated costs.

To examine the impact of a Medicaid Home and Community-Based waiver on service utilization, costs, functional status, and survival.

To examine any substitutions of formal for informal home care.

**Action Steps:** Conduct interviews with participants in New Jersey Medicaid Waiver program.

Abstract data from Medicaid claims.

**Descriptions:** Health Care Costs and Utilization in AIDS Home Care.

***The National Strategy for HIV and AIDS -- AHCPR Appendix  
Draft for Department of Health and Human Services Review: 6.11.96***

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**FY 95:** \$394,557

**FY 96:** \$39,455

**FY 97:**

**Populations Served:** Medicaid recipients with AIDS in New Jersey.

**Constituency Involvement:** Persons with AIDS residing at home or in community facilities.

**Unmet Need:** None.

**Objective 6:** To examine types of ambulatory care providers used to treat HIV infection, patterns of transitions between ambulatory provider types, and service utilization and costs for pediatric HIV patients.

**Action Steps:** Analyze Medicaid claims and eligibility data from New York State Medicaid files.

**Descriptions:** Ambulatory Care for HIV/AIDS, Models and Outcomes.

**FY 95:** \$392,103 (from FY94 funds).

**FY 96:** \$0

**FY 97:**

**Populations Served:** New York State Medicaid recipients.

**Constituency Involvement:** N/A

**Unmet Need:** None.

**Objective 7:** To assess the impact of antiretroviral, antimicrobial, and prophylactic treatment on the natural history of HIV infection, and the effect of pharmaceutical therapies on service utilization, costs, and clinical outcomes.

**Action Steps:** Develop clinical database linked to Medicaid claims data.

**Descriptions:** Outcomes of Pharmaceutical Therapy in HIV Disease.

**FY 95:** \$527,287

**FY 96:** \$420,000

**FY 97:**

***The National Strategy for HIV and AIDS -- AHCPR Appendix  
Draft for Department of Health and Human Services Review: 6.11.96***

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**Populations Served:** HIV-infected population in Maryland.

**Constituency Involvement:** N/A

**Unmet Need:** None.

**Objective 8:** To study issues of costs and quality of care, with a focus on women and children, examine trends and variation in adherence to scientifically-based clinical guidelines, and study predictors of variation in treatment, by patient, physician, and practice setting characteristics.

**Action Steps:** Analyze Medicaid claims and eligibility data, supplemented with AIDS Registry data.

**Descriptions:** Quality and Costs of Care for HIV Infected Medicaid Patients.

**FY 95:** \$110,704 (from 1994 funds)

**FY 96:** \$0

**FY 97:**

**Populations Served:** New Jersey Medicaid recipients.

**Constituency Involvement:** N/A

**Unmet Need:** None.

**Objective 9:** To develop an econometric framework for the simultaneous study of health care usage and survival, and synthetic estimates of per-person lifetime costs of HIV disease for various groups of HIV-infected individuals.

**Action Steps:** Formulate statistical models and associated computer software.

**Descriptions:** Developing Econometric Models to Estimate AIDS Costs.

**FY 95:** \$248,126

**FY 96:** \$8,002

**FY 97:**

**Populations Served:** Participants in the AIDS Costs and Service Utilization Survey, with potential extensions to all persons with HIV disease.

***The National Strategy for HIV and AIDS -- AHCPR Appendix  
Draft for Department of Health and Human Services Review: 6.11.96***

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**Constituency Involvement:** N/A

**Unmet Need:** None.

**Objective 10:** To identify personal and institutional factors that shape physicians' willingness to care for HIV-infected patients.

**Action Steps:** Conduct the third in a series of interviews with physicians, who are currently in their sixth post-graduate year.

**Descriptions:** Determinants of Physicians' AIDS-Related Practice Behavior

**FY 95:** \$216,054 (from 1994 funds)

**FY 96:** \$0

**FY 97:**

**Populations Served:** Persons with AIDS

**Constituency Involvement:** Physicians

**Unmet Need:** None.

**Objective 11:** Continuing work previously completed with AHCPR support, compare outcomes of inpatient care for AIDS provided by dedicated AIDS units versus scattered-bed approaches.

**Action Steps:** Expand upon original comparative multi-site observational study of 20 hospitals.

**Descriptions:** Outcomes of Hospital Dedicated AIDS Units

**FY 95:** \$180,649

**FY 96:** \$214,086

**FY 97:**

**Populations Served:** 1300 patients receiving services in study hospitals.

**Constituency Involvement:** N/A

**Unmet Need:** None.

***The National Strategy for HIV and AIDS -- AHCPR Appendix  
Draft for Department of Health and Human Services Review: 6.11.96***

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**Objective 12:** Obtain and analyze data on inpatient hospital utilization by people with HIV infection.

**Action Steps:** Assemble and will analyze database of hospital discharge data from all hospitals in 12 States.

**Descriptions:** Hospital Cost and Utilization Project

**FY 95:** \$500,000

**FY 96:** \$284,164

**FY 97:**

**Populations Served:** Patients with AIDS receiving inpatient care in hospitals in 12 states.

**Constituency Involvement:** N/A

**Unmet Need:** None.

## **PREVENTION**

**Agency:** Agency for Health Care Policy and Research

**Goal:** To provide national estimates of the cost and use of HIV-related prevention services.

**Objective 1:** To examine the effects of an in-home computer information and support system on health care costs and quality of life.

**Action Steps:** Half of three hundred patients with advanced HIV infection are provided with in-home computer system; the other half receive no intervention. Effects of this system are assessed with respect use of prophylactic treatments, early detection of infections, and quality of life.

**Descriptions:** Demonstrating Computer Support Impact on AIDS Patients

**FY 95:** \$704,655

**FY 96:** \$36,577

**FY 97:**

**Populations Served:** 300 volunteers with advanced HIV infection.

**Constituency Involvement:** Persons with HIV

**Unmet Need:** None.

**Objective 2:** Evaluate the cost-effectiveness of alternative strategies for preventing HIV-related opportunistic infections.

**Action Steps:** Embed clinical and cost data from randomized trials and observational cohorts into a comprehensive decision-analytic, cost-effectiveness model.

**Descriptions:** Cost-Effectiveness of Preventing AIDS Complications.

**FY 95:** \$346,420

**FY 96:** \$19,731

**FY 97:**

**Populations Served:** Persons with HIV.

***The National Strategy for HIV and AIDS -- AHCPR Appendix  
Draft for Department of Health and Human Services Review: 6.11.96***

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**Constituency Involvement:** N/A

**Unmet Need:** None.

## **TRANSLATION OF RESEARCH INTO PRACTICE**

**Agency:** Agency for Health Care Policy and Research

**Goal:** To expedite the dissemination of data from research.

**Objective 1:** To provide accurate information concerning current Federally approved treatments for HIV-related conditions.

**Action Steps:** Through the use of reference specialists, provide appropriate treatment information to callers, drawing on NLM's database of AHCPR guidelines, in addition to NIH, CDC and other Federal agency guidelines and consensus statements.

**Descriptions:** AIDS Treatment Information Service

**FY 95:** \$75,000

**FY 96:** \$75,000

**FY 97:**

**Populations Served:** HIV-positive individuals, primary care practitioners, case managers, and allied health professionals.

**Constituency Involvement:** HIV-positive individuals and advocacy groups as well as health care professionals.

**Unmet Need:** N/A

**Objective 2:** To provide accurate information to service providers and consumers concerning management of early HIV infection.

**Action Steps:** A panel of experts reviewed relevant literature and summarized findings into specific clinical practice guidelines, which stress the importance of preventing HIV-related opportunistic infections and the link between prevention and early diagnosis. Approximately 2.7 million copies of guideline-related documents have been distributed.

**Descriptions:** Dissemination of AHCPR's HIV-Related Clinical Guidelines.

**FY 95:** 30,000 (to AIDS clearinghouse)

**FY 96:** 30,000 (to AIDS clearinghouse)

**FY 97:**

***The National Strategy for HIV and AIDS -- AHCPR Appendix  
Draft for Department of Health and Human Services Review: 6.11.96***

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**Populations Served:** Clinical practitioners, individuals with HIV infection, and those persons caring for persons with HIV.

**Constituency Involvement:** Clinicians, HIV positive persons, and caregivers.

**Unmet Need:** N/A

**Objective 3:** To assess effective and ineffective dissemination strategies employed by community-based HIV education programs.

**Action Steps:** Examined organizational strategies used by several community-based HIV education agencies. Completed in FY 96.

**Descriptions:** Effective Strategies of AIDS Programs in San Francisco.

**FY 95:** \$198,883 (from 1994 funds)

**FY 96:** \$0

**FY 97:**

**Populations Served:** Community-based HIV education agencies in San Francisco

**Constituency Involvement:** Advocacy organizations and persons with HIV were included in the research.

**Unmet Need:** N/A

**Objective 4:** This guide and related materials will inform pregnant women with HIV about the use of zidovudine (AZT) for the prevention of perinatal HIV infection.

**Action Steps:** Developed guide and related materials which describe the recommendations of the PHS Task Force on the Use of Zidovudine to Reduce Perinatal Transmission of HIV, based on results of AIDS Clinical Trials Group 076. Provided the information in a format and reading level that consumers can comprehend.

**Descriptions:** Development of Consumer Guide on Use of Zidovudine for the Prevention of Perinatal HIV Infection (076 Guide).

**FY 95:** \$15,000

**FY 96:** \$50,000

**FY 97:**

***The National Strategy for HIV and AIDS -- AHCPR Appendix  
Draft for Department of Health and Human Services Review: 6.11.96***

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**Populations Served:** Pregnant women and women of child-bearing age who have HIV.

**Constituency Involvement:** HIV infected individuals and advocacy groups are involved in the development and review of the guide. The guide is cosponsored by multiple Federal and non-Federal agencies.

**Unmet Need:** N/A

## **PREVENTION**

**Agency:** The Centers for Disease Control and Prevention

**Goal:** More accurately monitor the HIV epidemic and provide data to assess and direct prevention programs by strengthening existing systems and develop new surveillance systems.

**Objectives:** Implement projects that evaluate and expand the uses of HIV infection and AIDS case surveillance and sero-surveillance data so that these data systems can more effectively guide public health policy and provide relevant information necessary to direct and evaluate prevention activities.

Improve understanding of the natural history of HIV infection as well as the risk factors and protective factors for sexual, drug-related, perinatal, and healthcare worker related HIV transmission in order to develop more effective prevention strategies for all affected populations.

**Action Steps:** Evaluate HIV infection reporting systems (named, anonymous, unique identifier) used nationally for their ability to monitor the epidemic, provide linkages to medical and social services, and to assess their impact on a person's decision to be tested;

Characterize high risk behaviors of persons with evidence of recent HIV infection such as persons with documented HIV seroconversion, high CD4+ counts, or diagnosis of HIV infection in adolescents;

Assess the impact of public health guidelines and recommendations and prevention efforts;

Characterize persons co-infected with TB and HIV;

Evaluate ways to improve the completeness and quality of risk ascertainment on persons reported with HIV and AIDS;

Identify and characterize previously unreported AIDS cases among deaths investigated by local medical examiners to assess the impact of under-diagnosis of AIDS cases on AIDS surveillance among disadvantaged populations that often do not receive adequate health care;

Test the efficiency of new techniques for reporting HIV and AIDS surveillance data from health care providers and laboratories to health departments;

***The National Strategy for HIV and AIDS -- CDC Appendix  
Draft for Department of Health and Human Services Review: 6.11.96***

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Collect additional data on persons reported through HIV/AIDS surveillance which may be important for the planning and evaluation of prevention and care programs, such as social/economic status, levels of disabilities, drug use history, sex behavior history, utilization of HIV testing and medical care services, and reproductive history in women;

Assess the interrelationship of behaviors, HIV markers and surrogates, and their potential role in surveillance systems;

Assess the interaction of socioeconomic, behavioral, and biologic factors in HIV transmission;

Determine the role of female-specific biological factors that are linked to acquisition and transmission of HIV infection and that influence the course of HIV disease;

Determine factors contributing to the efficiency of sexual transmission of HIV;

Assess the risk of transmission of HIV and TB from HIV-infected health-care worker to patient and vice versa;

Develop systems to monitor the emergence of multidrug-resistant TB in the HIV infected;

Continue to develop improved methods for projecting or modeling the HIV epidemic;

Develop methods to differentiate HIV-specific antibodies generated in participants in HIV vaccine trials from those generated in response to HIV infection;

Develop methods to identify potential cases of HCW-to-patient transmission;

Expand HIV reporting systems to collect information about primary and secondary HIV prevention services needed and received by HIV-positive clients (in collaboration with HRSA);

Work with providers and users of lab services to develop & implement systems which provide assurance that the capacity and quality requirements for HIV testing are met;

Work with international partners to study TB, implement vaccine trials, enhance clinical management, assess prevention efficacy, and improve program management of HIV/AIDS.

Develop methods to evaluate the use of HIV infection and AIDS surveillance systems to assess early intervention strategies.

***The National Strategy for HIV and AIDS -- CDC Appendix  
Draft for Department of Health and Human Services Review: 6.11.96***

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**Descriptions:** Many of the activities in the above-cited action steps are carried out through cooperative agreements with state and local health departments. In addition, specialized projects and studies also serve to focus attention on these activities, these include: Evaluation of HIV Infection Reporting Systems Project, Recent HIV Infection Projects, Surveillance to Evaluate Prevention Projects, Adult Spectrum of Disease Project, the TB Project, Mode of Transmission Validation Project, the Medical Examiner Study, and the Enhancement of AIDS Surveillance Efficiency Project.

**FY 95:** \$141,076,000

**FY 96:** \$140,917,000

**FY 97:**

**Populations Served:** All major racial, ethnic, and risk groups.

**Constituency Involvement:** There is regular consultation with national, state, and local public health officials and many other relevant organizations such as HIV-related community-based organizations.

**Unmet Need:** The current system does not provide for adequate surveillance of risk behaviors that contribute to HIV transmission, nor does it provide an accurate means for monitoring HIV incidence.

## **PREVENTION**

**Agency:** The Centers for Disease Control and Prevention

**Goal:** Increase the public understanding of, involvement in, and support for HIV prevention.

**Objectives:** Provide leadership in HIV and STD prevention by (1) establishing sustained and active national agenda through the media; (2) promoting credible messages based on science through credible channels; and (3) encouraging and supporting prevention efforts at the local level.

Establish a collaboration of partners composed of national, State, and local organizations to facilitate (1) diffusing social marketing principles applied to HIV and STD prevention at the local level; (2) identifying and promoting mechanisms to exchange technology and information; and (3) developing guidelines for applying social marketing principles to local HIV and STD prevention.

Apply social marketing principles at the local level for the purpose of (1) demonstrating the participatory social marketing process (i.e., skills and resources needed to effectively engage the community); (2) measuring the effects of behavior-based social marketing interventions; and, (3) documenting the lessons learned.

Facilitate the application of prevention marketing principles in CDC-funded community planning efforts by (1) promoting guidelines for consideration of these principles at the local level for prevention interventions and (2) providing interactive technical assistance on social marketing technology principles (or prevention marketing) to public health agencies as well as HIV Prevention Community Planning Groups.

Promote HIV prevention as a relevant issue in business settings.

Provide and promote a network of resources and referrals to assist in implementing the Business Responds to AIDS (BRTA) Comprehensive HIV/AIDS Workplace Program.

Market the comprehensive workplace HIV/AIDS program to business.

Establish and execute a research agenda to formulate and assess strategies and resources to advance the knowledge of effective workplace HIV programs.

**Action Steps:** Monitor changes in public knowledge about how HIV is and is not transmitted;

***The National Strategy for HIV and AIDS -- CDC Appendix  
Draft for Department of Health and Human Services Review: 6.11.96***

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Develop methodologies to measure community mobilization or changes in institutional behavior in relation to mass media public information and education programs;

Develop new mass media messages, in collaboration with the public health systems and with international, national, state, and local private sector organizations and agencies;

Expand the relationship between CDC and the entertainment industry to improve messages and role modeling for HIV prevention;

Develop communication interventions with appropriate organizations to ensure that consistent, accurate HIV prevention information is provided to the public;

Develop community coalitions for HIV prevention;

Coordinate and disseminate information messages through the media that explain new scientific findings and policies concurrent with the release of new scientific information;

Develop leadership of health/education officials to effectively deliver HIV prevention messages through partnerships;

Evaluate the role of communications in changing individual knowledge, community norms, and individual behavior through establishment of model programs;

Expand the relationship between CDC and academic experts in mass communications to develop methods for measuring the impact of mass media on individual and community behaviors;

Develop ways of measuring the mobilization of community groups, i.e., changes in community norms, capacity;

Monitor business policies and employee education programs regarding HIV/AIDS;

Implement a BRTA initiative to develop HIV prevention and service programs for the workplace and the community;

Sponsor and participate in national meetings of businesses and religious, civic, medical, social, and voluntary agencies which conduct HIV prevention and service programs.

**Descriptions:** Many of the activities cited above are carried out at local demonstration sites and in coordination with community planning efforts. In addition, specialized projects and

***The National Strategy for HIV and AIDS -- CDC Appendix  
Draft for Department of Health and Human Services Review: 6.11.96***

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studies also serve to focus attention on these activities, these include projects entitled: National Health Communications, Prevention Collaborative Partners, the CDC National AIDS Clearinghouse, and the CDC National AIDS Hotline, and the Prevention Marketing Initiative.

Also, linkage efforts with business, labor, and community groups have received special attention. The Business Responds to AIDS (BRTA) and Labor Responds to AIDS (LRTA) programs have focused on issues such as: HIV/AIDS workplace policies, supervisor and labor leader training, employee education, employee family education, and community service and volunteerism. Partnerships have also been forged among a variety of communities including business, labor, religious, voluntary and the media. And, national and regional minority organizations have also been sought out in forging these important linkages.

**FY 95:** \$45,970,000

**FY 96:** \$46,869,000

**FY 97:**

**Populations Served:** All segments of the population including all major racial and ethnic groups, young persons (18-25), persons engaging in behaviors that place them at risk for HIV infection, and business and labor leaders including their employees and families.

**Constituency Involvement:** Regular consultation with leaders from over 200 prevention collaborative partners composed of national, state, and local organizations and over 50 business and labor partners.

**Unmet Need:** There is a need for more effective use of social marketing principles in HIV prevention programs, further implementation of strategies to promote adoption of BRTA and LRTA comprehensive programs. There is also an increased need for family education materials, more effective materials to encourage abstinence and other prevention behaviors, and more HIV prevention materials for use by religious communities.

## **PREVENTION**

**Agency:** The Centers for Disease Control and Prevention

**Goal:** Prevent risk behaviors that can cause HIV infection and related health problems in school age children and college age persons through implementation of comprehensive school health education programs.

**Objectives:** Increase by 15 percent the proportion of school districts that require age-appropriate HIV education at each grade level, K-12, especially at grades 9-12, preferably as part of a comprehensive school health education program.

Increase by 15 percent the proportion of colleges and universities that provide HIV education for students and staff, preferably as part of an institution-wide health promotion program.

Decrease by 10 percent at each grade level the proportion of 9th to 12th grade students who report they have engaged in sexual intercourse.

Among 9th to 12th grade students who report they have engaged in sexual intercourse, decrease by 10 percent the proportion who report they have engaged in sexual intercourse during the past 3 months.

Among 9th to 12th grade students who report they have engaged in sexual intercourse during the past 3 months, increase by 10 percent the proportion who report they used a condom at last intercourse.

Decrease by 10 percent the proportion of 9th to 12th grade students who report they have injected illicit drugs.

**Action Steps:** Monitor state-level policy and program requirements that support effective HIV education within comprehensive school health education programs (CSHEPs);

Monitor district-level policy and program requirements that support effective HIV education within comprehensive school health education programs;

Monitor the prevalence of behaviors that cause HIV infection and related health problems among school and college students;

Implement and revise as necessary, CDC guidelines for effective school health education to prevent the spread of HIV infection;

***The National Strategy for HIV and AIDS -- CDC Appendix  
Draft for Department of Health and Human Services Review: 6.11.96***

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Enhance the capacity of state and local educational agencies to develop and implement effective HIV education within CSHEPs;

Enhance the capacity of colleges and universities to provide HIV education for students and staff, preferably as part of an institution-wide health promotion program;

Ensure the integration of education to prevent HIV infection, other STDs and the use of alcohol and other drugs among youth;

Strengthen the capabilities of state and local departments of education and health to collaboratively help schools, colleges and universities implement effective HIV education programs for youth;

Increase the effectiveness of HIV education for youth served by state and local departments of education and college and universities through the efforts of selected national organizations;

Enhance the capacity of state and local agencies to help prevent HIV infection and HIV-related problems among youth through the efforts of training and demonstration centers established for state and local departments of education and colleges and universities;

Establish teacher training coordinators in every interested state to help teachers provide effective HIV education within a CSHEP;

Identify and disseminate, through training and demonstration centers and through teacher training coordinators, HIV education programs that have been shown to be effective in reducing behaviors that cause HIV infection and related health problems;

Synthesize and apply the results of research to increase the effectiveness of HIV prevention education for youth;

Conduct formative evaluations of state and local departments of education policies, curricula, teacher training, and school efforts to prevent behaviors that cause HIV infection and related health problems;

Develop a standardized report for each state to profile the nature of priority health problems and risk behaviors among youth in that state and school efforts to prevent these problems and behaviors;

Conduct evaluations of the effectiveness of existing school-based interventions to reduce

***The National Strategy for HIV and AIDS -- CDC Appendix  
Draft for Department of Health and Human Services Review: 6.11.96***

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behaviors that result in HIV infection and related health problems;

Develop state-of-the-art school-based interventions and evaluate their effectiveness in reducing behaviors that result in HIV and related health problems; and

Conduct and apply meta-evaluations of existing research data about the effectiveness of school-based interventions in reducing health risks behaviors among adolescents.

**Descriptions:** Funding and technical assistance for state and local educational agencies is provided through several avenues including national organizations, colleges and universities, and teacher training sites. There is also support for youth surveys and projects to reach out-of-school youth.

**FY 95:** \$48,215,000

**FY 96:** \$48,162,000

**FY 97:**

**Populations Served:** Young persons engaging in behaviors that place them at risk for acquiring HIV through sexual exposure, including all major racial and ethnic groups. All school- and college-aged youth regardless of school enrollment status.

**Constituency Involvement:** Consultation with a wide range of constituency groups was established to: (1) improve existing programmatic efforts; (2) improve assistance and resources provided by CDC; and, (3) explore strategies that the Nation might take to improve the health status of young people. These groups include representatives from: (1) every state education agency and 18 local education agencies; (2) national nongovernmental health or education organizations, 3) colleges and universities, 4) state public health departments, as well as young people themselves. Meetings included an annual constituency meeting, quarterly training programs, and communication through an electronic bulletin board and network.

**Unmet Need:** Not all youth are accessible through existing institutional-based efforts, and currently not all states monitor youth health-risk behaviors.

## **PREVENTION**

**Agency:** The Centers for Disease Control and Prevention

**Goal:** Prevent or reduce behaviors or practices which place individuals at risk of HIV infection, and for HIV positive individuals, place others at risk.

**Objectives:**

**What is the baseline for the below-listed targets? How will they be measured?**

At least 90 percent of individuals with known HIV infection will be abstinent or will have used a condom at last sexual intercourse, and at least 50 percent of individuals who have engaged in high-risk sexual behaviors within the past 12 months will be abstinent, in a mutually monogamous relationship, or have used a condom at last sexual intercourse.

At least 75 percent of injecting drug users will have stopped injecting drugs or used sterile or decontaminated injection equipment at last injection.

At least 80 percent of the health care and public safety workplaces will implement programs and procedures for preventing HIV transmission at work sites.

Reduce unintended pregnancies to no more than 40 percent of pregnancies among women with or at risk for HIV infection.

The number of individuals donating blood and found to be infected with HIV at the time of donation will decrease by 50 percent through self-deferral.

Among selected populations of youth in high-risk situations, increase by 10 percent the proportion who report they used a condom at last sexual intercourse.

**Action Steps:** Collaborate with prevention partners to assess risk behaviors and practices in selected communities;

Identify barriers to implementation of HIV prevention programs at community, state, and national levels;

Collaborate with selected communities in developing and implementing a model behavioral intervention program that comprehensively addresses community needs and uses available community resources and prevention partners in selected sites;

***The National Strategy for HIV and AIDS -- CDC Appendix  
Draft for Department of Health and Human Services Review: 6.11.96***

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Design, develop, and test effective community-level interventions to change risk behaviors through altering community norms and values to support healthy behaviors;

Expand the community's capacity to plan, implement, and evaluate culturally competent and linguistically specific HIV prevention guidelines and programs tailored to the needs of specific populations;

Enhance the capacity of CDC staff to plan, administer, and evaluate behavioral change strategies and community-based interventions to provide public health leadership and assist our prevention partners in designing and managing effective strategies for HIV prevention programs;

Enhance the capacity of local health departments and other relevant community agencies to collaboratively provide effective HIV education for youth in high-risk situations;

Establish scientifically-based evaluation components for HIV prevention activities; and

Use evaluation of components to design or refine HIV prevention programs and/or redirect HIV prevention resources.

**Descriptions:** Several mechanisms are employed for achieving the goals and objectives cited above. These include cooperative agreements with state and local health departments, in addition to direct funding of community-based organizations, national organizations, and national minority organizations. HIV intervention research studies are also supported.

**FY 95:** \$185,666,000

**FY 96:** \$209,764,000

**FY 97:**

**Populations Served:** All major racial and ethnic groups in addition to persons engaging in behaviors that place them at risk for acquiring HIV.

**Constituency Involvement:** A major avenue for constituency involvement is the HIV Prevention Community Planning Process. Through this mechanism, state and local health departments form community planning groups to assist in developing HIV prevention plans. In addition, there is regular and extensive consultation with representatives from state and local health departments, community planning groups, and national organizations.

**Unmet Need:** There is currently a lack of behavioral risk surveillance data for program planning and evaluation purposes. There is also a need to develop a more effective

***The National Strategy for HIV and AIDS -- CDC Appendix  
Draft for Department of Health and Human Services Review: 6.11.96***

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application of behavioral science findings to HIV prevention programs. And there is a special need to develop and maintain prevention efforts that target high risk women, youth and gay men of color.

## **PREVENTION**

**Agency:** The Centers for Disease Control and Prevention

**Goal:** Increase individual knowledge of serostatus and strengthen systems for successful referral to early intervention services.

**Objectives:**

**What is the baseline for the below-listed targets?**

At least 85 percent of the estimated 800,000 to 1,000,000 HIV-infected individuals will know their HIV serostatus.

At least 90 percent of health care sites receiving public funds and serving at-risk persons will provide appropriate HIV counseling and testing services.

At least 80 percent of known HIV infected individuals, either directly or through referral, will receive primary and secondary prevention services.

**Action Steps:** Working with governmental and nongovernmental partners, enhance community-level assessments of needed primary & secondary prevention services;

Identify opportunities for common HIV prevention data collection and development of uniform data sets;

Integrate HIV prevention services into standards of care for the diagnosis and treatment of HIV disease;

In collaboration with the FDA, develop, test, and implement rapid HIV testing procedures;

Strengthen the capacity of state, and local health departments to provide partner notification services to private health care providers offering HIV counseling & testing;

Develop alternative methods to provide HIV counseling and testing services;

Work with professional groups, hospitals, and state health departments to ensure that health care workers receive adequate training on primary and secondary HIV prevention (in collaboration with HRSA);

Study the impact of discrimination as a barrier to prevention services;

***The National Strategy for HIV and AIDS -- CDC Appendix  
Draft for Department of Health and Human Services Review: 6.11.96***

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Assist publicly funded counseling and testing sites establish selection criteria and systems for monitoring the quality of referral laboratories;

Interview persons newly diagnosed with HIV infection to identify missed opportunities for earlier diagnosis and CD4+ testing;

Conduct a study of incident AIDS cases to determine what services HIV-positive clients are receiving over time to identify service gaps (in collaboration with HRSA); and

Provide guidelines and training to HIV counselors to improve the quality of counseling.

**Descriptions:** Counseling, testing, referral partner notification programs are supported as part of cooperative agreements with state and local health departments.

**FY 95:** \$169,035,000

**FY 96:** \$179,006,000

**FY 97:**

**Populations Served:** All major racial and ethnic groups and persons engaging in behaviors that place them at risk for acquiring HIV.

**Constituency Involvement:** A major avenue for constituency involvement is the HIV Prevention Community Planning Process. Through this mechanism, state and local health departments form community planning groups to assist in developing HIV prevention plans. In addition, there is regular and extensive consultation with representatives from state and local health departments, community planning groups, and national organizations.

**Unmet Needs:** There is a need for more effective long-term intervention programs for HIV positive individuals in addition to a lack of resources for supporting comprehensive referral and data monitoring systems. Also, there is a need to determine the best balance between CTRPN programs and other HIV prevention strategies.

## **RESEARCH**

**Agency:** Food and Drug Administration

**Goal:** Ensure the safety and effectiveness of HIV-related therapeutic agents.

**Objective:** Expedite access and approval of safe and effective drugs and biologics.

**Action Steps:** Encourage quality applications and data submissions to review division to ensure timely and efficient pre- and postmarket review.

**Descriptions:** Conduct meetings with sponsors to discuss drug development plans, expanded access programs, and accelerated approval options.

Facilitate scientific review of drugs and biologics by FDA advisory committees.

**FY 95:** \$25,235,000

**FY 96:** \$25,536,000

**FY 97:**

**Populations Served:** All persons who may benefit from approved therapeutic agents.

**Constituency Involvement:** The FDA depends on scientific advisory committees to provide independent expert advice to the agency in its evaluation of regulated products. These committees are composed of representatives from academia, research, government, industry and patient advocates.

**Unmet Need:** With the passage of Prescription Drug Use Fee Act of 1992, the FDA has been able to expeditiously review HIV/AIDS related therapeutic applications. With the continuation of the provisions in the Act, the FDA will be able to continue expeditious reviews.

## **RESEARCH**

**Agency:** Food and Drug Administration

**Goal:** Ensure the safety and effectiveness of HIV-related preventive and therapeutic vaccines.

**Objective:** Expedite regulatory review of promising products for preventive and therapeutic vaccines.

**Action Steps:** Expand partnership between FDA and its counterparts from outside organizations involved in vaccine development.

**Descriptions:** Encourage early consultation with sponsoring companies, develop guidance documents, exchange information, and work with other agencies and international organizations. Facilitate scientific review by FDA advisory committees.

**FY 95:** \$11,863,000

**FY 96:** \$12,005,000

**FY 97:**

**Populations Served:** All persons who may benefit from approved preventive and therapeutic vaccines.

**Constituency Involvement:** The FDA depends on scientific advisory committees to provide independent expert advice to the agency in its evaluation of regulated products. These committees are composed of representatives from academia, research, government, industry, and patient advocates.

**Unmet Need:** With the passage of Prescription Drug Use Fee Act of 1992, the FDA has been able to expeditiously review HIV/AIDS related therapeutic applications. With the continuation of the provisions in the Act, the FDA will be able to continue expeditious reviews.

## **RESEARCH**

**Agency:** Food and Drug Administration

**Goal:** Ensure the effectiveness of test methodologies for HIV detection and measurement.

**Objective:** Expedite improved test methodologies (such as diagnostic reagents and test kits) for HIV detection, confirmation, and viral load measurement.

**Action Steps:** Ensure timely and efficient pre- and postmarket review.

**Descriptions:** Encourage early consultation with sponsor and develop guidance documents. Facilitate scientific review of drugs and biologics by FDA advisory committees.

**FY 95:** \$8,732,000

**FY 96:** \$8,836,000

**FY 97:**

**Populations Served:** All persons who may benefit from approved test methodologies for HIV detection and measurement.

**Constituency Involvement:** The FDA depends on scientific advisory committees to provide independent expert advice to the agency in its evaluation of regulated products. These committees are composed of representatives from academia, research, government, industry, and patient advocates.

**Unmet Need:** With the passage of Prescription Drug Use Fee Act of 1992, the FDA has been able to expeditiously review HIV/AIDS related therapeutic applications. With the continuation of the provisions in the Act, the FDA will be able to continue expeditious reviews.

## **PREVENTION**

**Agency:** Food and Drug Administration

**Goal:** Reduce transfusion-transmitted HIV infection.

**Objective:** Ensure supply and safety of the national blood supply.

**Action Steps:** Establish policies, expedite review of product applications, conduct approval inspections, oversee surveillance, and support enforcement activities.

**Descriptions:** Encourage high risk donors to exclude themselves; update list of unsuitable donors; quarantine and test blood; investigate incidents to identify, and rectify common errors in blood banks.

**FY 95:** \$17,458,000

**FY 96:** \$17,667,000

**FY 97:**

**Populations Served:** All persons who may receive blood or blood products.

**Constituency Involvement:** The FDA depends on scientific advisory committees to provide independent expert advice to the agency in its evaluation of regulated products. These committees are composed of representatives from academia, research, government, industry, and patient advocates.

**Unmet Need:** With the passage of Prescription Drug Use Fee Act of 1992, the FDA has been able to expeditiously review HIV/AIDS related therapeutic applications. With the continuation of the provisions in the Act, the FDA will be able to continue expeditious reviews.

## **RESEARCH**

**Agency:** Food and Drug Administration

**Goal:** Ensure the safety and effectiveness of HIV-related medical devices.

**Objective:** Expedited access and approval of safe and effective medical devices.

**Action Steps:** Encourage quality application and data submissions to ensure timely and efficient pre- and postmarket review.

**Descriptions:** Conduct meetings with sponsors on study design; produce guidance documents. Facilitate scientific review of drugs and biologics by FDA advisory committees.

**FY 95:** \$9,457,000

**FY 96:** \$9,570,000

**FY 97:**

**Populations Served:** All persons who may benefit from approved HIV-related medical devices.

**Constituency Involvement:** The FDA depends on scientific advisory committees to provide independent expert advice to the agency in its evaluation of regulated products. These committees are composed of representatives from academia, research, government, industry, and patient advocates.

**Unmet Need:** The FDA depends on scientific advisory committees to provide independent expert advice to the agency in its evaluation of regulated products. These committees are composed of representatives from academia, research, government, industry, and patient advocates.

## **PREVENTION**

**Agency:** Health Care Financing Administration

**Goal:** Reduce perinatal transmission among Medicaid-eligible women.

**Objective 1:** Enable Medicaid-eligible pregnant women to make informed decisions regarding receiving AZT.

**Action Steps:** Develop, obtain, and distribute brochures and other materials describing current guidelines for the use of AZT during pregnancy for preventing perinatal transmission, and Medicaid eligibility and coverage to Medicaid eligible women in RI, DE, FL, and NJ.

**Descriptions:** Establish a consumer-oriented educational campaign in key states with high HIV prevalence rates among women.

**FY 95:** \$50,000 (Federal share)

**FY 96:**

**FY 97:**

**Populations Served:** HIV positive women eligible for Medicaid coverage.

**Constituency Involvement:** Significant consultation with high-risk pregnant women and their advocates.

**Unmet Need:** The pilot project will not initially include women of unknown or negative HIV serostatus. This project should be extended nationwide.

## **CARE AND SERVICES**

**Agency:** Health Care Financing Administration

**Goal:** Provide quality home health care for HIV positive Medicaid and Medicare beneficiaries.

**Objective:** Provide quality standards for appropriate home health care services and treatment of HIV disease.

**Action Steps:** Identify current home health care practices through literature review and survey of best practices.

**Descriptions:** Develop and implement quality standards for appropriate home health care for HIV positive beneficiaries in partnership with private sector organizations and PHS agencies;

Develop directives in implementation of developed guidelines.

**FY 95:** \$25,000 (Conferences and materials)

**FY 96:**

**FY 97:**

**Populations Served:** HIV positive Medicaid and Medicare beneficiaries receiving home health care.

**Constituency Involvement:** Significant constituent consultation throughout course of project development.

**Unmet Need:** Implementation of directives dependent on nature and resources of each project partner.

## **CARE AND SERVICES**

**Agency:** Health Care Financing Administration

**Goal:** Provide primary health care to Medicaid-eligible HIV positive persons.

**Objective:** Provide quality primary health to Medicaid-eligible HIV positive persons.

**Action Steps:** Assess state compliance with Medicaid program standards. Review and evaluate waiver applications. Encourage compliance with changes in the standard-of-care.

**Description:** Medicaid primary health care services.

**FY 95:** \$1,640,000,000 (Federal share)

**FY 96:** \$1,800,000,000 (Federal share)

**FY 97:**

**Populations Served:** HIV positive Medicaid-eligible persons.

**Constituency Involvement:** Information and activities routinely discussed with external groups at meetings and conferences.

**Unmet Need:** ????

## **CARE AND SERVICES**

**Agency:** Health Resources and Services Administration

**Goal:** Increase the number of competent primary care providers willing to care for HIV positive persons.

**Objective:** To increase the number of health care providers who are effectively educated and motivated to counsel, diagnose, treat, and manage individuals with HIV infection.

**Action Steps:** Support didactic and clinical training activities for primary health care providers in collaboration with Federal, state, and local HIV care programs;

Disseminate state-of-the art HIV information to providers; and

Develop and coordinate distribution of HIV provider materials.

**Descriptions:** A significant source of training takes place under the guidance of AIDS Education and Training Centers. In addition there are quarterly interactive conference calls with experts and providers, the National HIV Telephone Consultation Service (Warmline), phone consultation services, newsletters, bulletins, and provider guides for HIV priority areas (i.e., guidance for clinicians regarding the use of AZT for the prevention of perinatal transmission).

**FY 95:** \$16,300,000

**FY 96:** \$16,300,000

**FY 97:**

**Populations Served:** Health care providers and people living with HIV disease.

**Constituency Involvement:** Faculty, staff, advisory committees, training panels, persons living with AIDS, and academic faculty.

**Unmet Need:** Not enough adequately trained health care providers to meet patients demand, and, inadequate resources to meet provider training needs.

## **CARE AND SERVICES**

**Agency:** Health Resources and Services Administration

**Goal:** Reduce barriers to obtaining dental care for HIV positive persons.

**Objective:** Increase the number of dental practitioners who provide care to HIV positive patients.

Assist dental schools in meeting uncompensated costs associated in providing oral health care to HIV positive patients.

**Action Steps:** Provide reimbursement to dental schools of uncompensated costs incurred in treating patients with HIV.

**Descriptions:** The AIDS Dental Reimbursement Program is designed to reimburse accredited dental schools and post doctoral dental programs for the documented uncompensated costs incurred from providing oral health treatments to HIV positive patients.

**FY 95:** \$6,937,000

**FY 96:** \$6,937,000

**FY 97:**

**Populations Served:** Children and adults living with HIV.

**Constituency Involvement:** American Association of Dental Schools, American Association of Hospital Dentists, and American Dental Association. Are consumers included?

**Unmet Need:** Uncompensated costs that dental schools and hospitals incur are much more than the dollars available under the AIDS Dental Reimbursement Program.

## **CARE AND SERVICES**

**Agency:** Health Resources and Services Administration

**Goal:** Increase access to care and improve quality of life for persons living with HIV and AIDS.

**Objectives:** Through the Ryan White Comprehensive AIDS Resources Emergency (Care) Act (RWCA), improve accessibility and quality of care for all persons living with HIV.

Develop comprehensive and participatory planning processes at the state and local levels to guide funding allocation decisions.

Increase patient access to clinical research.

Establish quality guidelines and evaluate program effectiveness.

**Action Steps:** Support comprehensive outpatient, ambulatory health and support services, case management, and inpatient case management services that prevent unnecessary hospitalization or expedite discharge (RWCA Title I);

Support consortia to improve the quality and availability of health care, including home and community-based services, continuation of health insurance, purchase of AIDS drugs, direct provision of care for individuals and families living with HIV and AIDS (RWCA Title II);

Develop a minimum drug formulary for federally-assisted AIDS Drug Assistance Programs (ADAP --RWCA Title IV);

Support outpatient early intervention services for low-income medically underserved people in existing primary health care systems (RWCA Title III);

Support comprehensive care services for affected women, infants children, and youth in a comprehensive community-based, family-centered system of care (RWCA Title IV);

Support initial development of care systems linked to research for children, youth and women in 7 new communities; Please clarify the specific language in this section as it refers to WIN projects or other care systems.

Enhance linkages between care providers and sites where research is conducted;

***The National Strategy for HIV and AIDS -- HRSA Appendix  
Draft for Department of Health and Human Services Review: 6.11.96***

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Provide leadership, training, and technical assistance;

Convene youth and family leadership conferences and distribute findings;

Develop, distribute, and train providers on quality indicators and quality assurance guidelines for the clinical management of HIV disease;

Develop guidance for grantees in developing local strategies for changes in the standard-of-care; and

Evaluate program effectiveness through development of common evaluation criteria of CARE Act grants that address program delivery and program outcomes and establishment of evaluation measures that are unique to each Title.

**Descriptions:** Provide RWCA-supported services through individual grantees and service organizations. In addition to these broad-based efforts, support a variety of focused initiatives such as the adolescent research and clinical network and a cooperative agreement with Institute of Family-Centered Care to provide training and technical assistance to youth and families.

**FY 95:**       RWCA Title I:   \$356,500,000  
                  RWCA Title II: \$198,147,000  
                  RWCA Title III: \$ 52,318,000  
                  RWCA Title IV: \$ 26,000,000

**FY 96:**       RWCA Title I:   \$407,000,000  
                  RWCA Title II: \$221,897,000  
                  RWCA Title III: \$ 62,568,000  
                  RWCA Title IV: \$ 32,000,000

**FY 97:**       RWCA Title I:  
                  RWCA Title II:  
                  RWCA Title III:  
                  RWCA Title IV:

**Populations Served:** HIV positive individuals and their family members, low income persons with HIV/AIDS, pregnant women living with HIV/AIDS, neonates and children born to HIV positive women. In addition, RWCA grantees and planning councils receive technical assistance in conducting and evaluating their programs.

**Constituency Involvement:** The input and guidance of PLWAs and affected communities is gathered through a variety of avenues. Constituents are represented on the HRSA AIDS Advisory Committee, RWCA planning councils, with the input of broad-based local representation, guide local prioritization of RWCA funds.

The development of evaluation measures is a participatory process whereby local groups assist in the development of self-assessment tools. Local participants have early and ongoing involvement in all phases of data collection design, planning, and implementation.

In addition, focus groups, workshops, and discussion groups of PLWAs, providers of HIV care, State and local officials, researchers, and national groups such as the Pediatric AIDS Foundation and the National Positive Youth Alliance review proposed policies, program directives, and planning and evaluation activities to ensure constituency input.

**Unmet Need:** Access to mental health and substance abuse services. Funds for existing projects are inadequate to meet rapidly growing caseloads and increased demand care and training. Meeting these will require collaborative efforts with NIMH and SAMSHA in addition to expanding programs in general and especially for adolescents such as mental health, substance abuse, and family case management services. For the RWCA Title IV, funds were available for only one third of grant applicants in FY 1995. There is also a need for increased access to 1 % evaluation funds for service-related evaluations.

Moreover, 24 states lack comprehensive care systems for children, youth, women; funding of approximately \$1.8 million would support new planning and initial development projects in these states.

For frontline providers who may receive funding from several Federal Agencies, there is a need for improved coordination within and between Agencies. In addition, for example, to the lack of adequate resources for technical assistance and evaluation, there is also a need for improved planning and coordination of these activities between the various CARE activities and between Federal agencies.

## **CARE AND SERVICES**

**Agency:** Health Resources and Services Administration

**Goal:** Develop and evaluate innovative models of comprehensive managed care for persons living with HIV.

**Objective 1:** Develop models of comprehensive managed care networks that enroll a broad spectrum of primary care and psychosocial providers within the HIV continuum of care, and that provide patients and their families access to services.

**Action Steps:** Develop innovative models and disseminate results of evaluation.

**Descriptions:** Special Projects of National Significance (SPNS).

**FY 95:** \$2,092,302

**FY 96:** \$4,000,000

**FY 97:**

**Populations Served:** Persons living with HIV and their families.

**Constituency Involvement:** Primary care providers, community-based organizations, state and local health officials, Ryan White planning bodies, and persons living with HIV.

**Unmet Need:** There is a need for more effective linkages among community providers and financially stable medical sites.

**Objective 2:** Ensure that services provided under SPNS program are fully evaluated for both utilization and impacts and increase the evaluation capacity within community-based providers' organizations.

**Action Steps:** Increase emphasis on evaluation;

Increase the representation of evaluation researchers on review groups; and

Provide technical support for evaluation activities.

**Descriptions:** Evaluation of Special Projects of National Significance

***The National Strategy for HIV and AIDS -- HRSA Appendix  
Draft for Department of Health and Human Services Review: 6.11.96***

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**FY 95:** \$2,000,000

**FY 96:** \$4,000,000

**FY 97:**

**Populations Served:** SPNS grantees.

**Constituency Involvement:** Health care providers, evaluation researchers, and patient advocates.

**Unmet Need:** There is a need to develop more effective linkages between providers and evaluation researchers.

## **PREVENTION**

**Agency:** Health Resources and Services Administration

**Goal:** Reduce the perinatal transmission of HIV.

**Objective:** Enhance provider capacity to provide appropriate services for women at the community level.

Improve provider capacity for outreach, counseling, testing and care for women of childbearing age for early identification and linkage to care for pregnant women.

Enhance providers' abilities to provide AZT for HIV positive pregnant women.

Ensure funding and dissemination of innovative models of care that evaluate all of the major care and service goals listed in this plan: effectively educated providers, increased access to and quality of care, reduction of perinatal transmission of HIV.

**Action Steps:** Establish the Women's Initiative for HIV Care for Women and Reduction of Perinatal Transmission (WIN);

Establish ongoing WIN Steering Committee;

Provide technical assistance to grantees;

Conduct centralized training for all WIN sites with follow-up local training;

Collaborate with Association of Maternal & Child Health Programs (AMCHP) to develop local guidelines;

Establish MCHB working group to coordinate HIV risk reduction related efforts across programs;

Distribute counseling and testing guidance, AHCPR consumer brochure and video, and other PHS documents to MCHB community;

Review currently funded SPNS projects to identify gaps in project coverage for future Requests for Applications (RFAs); and

Evaluate sites.

***The National Strategy for HIV and AIDS -- HRSA Appendix  
Draft for Department of Health and Human Services Review: 6.11.96***

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**Descriptions:** Enhance outreach for HIV counseling and testing.

Improve service linkages for women of childbearing age in an ongoing care system and to reduce perinatal HIV transmission.

PHS 076 Implementation Plan.

**FY 95:** \$1,520,000

**FY 96:** \$1,800,000

**FY 97:**

**Populations Served:** CARE Act grantees. Adolescent and adult women and their infants, with special attention for pregnant women in addition to MCH and HIV providers.

**Constituency Involvement:** Health care providers, evaluation researchers, communication experts, and patient advocates. There is also consumer participation in WIN steering committee and projects' advisory board in addition to linkages with other HRSA grantees including those from RWCA and SPNS programs.

**Unmet Need:** Funds needed to provide more services in order to reach more women and enhance evaluation efforts and improve technical assistance and training.

In particular, it is critical to fund services (e.g., outreach, case finding, case management) that better link women of childbearing age with counseling and testing services and, after testing, with comprehensive medical, social, and support services and long-term followup for themselves and their families. Training non-HIV providers, particularly primary care, family practice, ob/gyn, and MCH providers, to perform women-sensitive counseling and testing, to deliver appropriate primary care for women with HIV, and to provide appropriate referrals for these women is another critical need. Funding is also needed for peer-support programs for these women and their families. While it should be our assumption that all women are at risk for HIV, it is important to recognize that certain groups of women (e.g., substance abusers, partners of substance abusers) are at special risk and need additional services in order to enter and remain in care.

## **PREVENTION**

**Agency:** Indian Health Service

**Goal:** Reduce the number of new infections among Federally recognized American Indians and Alaska Natives.

**Objective 1:** Maintain surveillance of HIV infection in American Indians and Alaska Natives.

**Action Steps:** Maintain timely and complete case reporting to appropriate local, state and national entities and the Indian Health Service (IHS) AIDS Prevention Activities Office.

**Descriptions:** Area AIDS Coordinators will be responsible for reporting.

**FY 95:** \$912,000

**FY 96:** \$912,000

**FY 97:**

**Populations Served:** Federally recognized American Indians and Alaska Natives.

**Constituency Involvement:** Local and National Indian Health Advisory Boards.

**Unmet Need:** ???

**Objective 2:** Maintain training and information activities to provide health education and risk reduction messages.

**Action Steps:** Teach empowerment skills at the individual and community level that will enhance the individual's ability to actualize assimilated knowledge as behavior change.

**Descriptions:** The changed behavior includes adjustments of beliefs and the formation of AIDS community-based task forces at the local level.

**FY 95:** \$2,321,000

**FY 96:** \$2,321,000

**FY 97:**

**Populations Served:** American Indians and Alaska Natives population, tribal leaders, women, youth, individuals practicing high risk behavior, and IHS/tribal health care workers

***The National Strategy for HIV and AIDS -- IHS Appendix  
Draft for Department of Health and Human Services Review: 6.11.96***

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**Constituency Involvement:** Local and National Indian Health Advisory Boards.

**Unmet Need:** ???

***The National Strategy for HIV and AIDS -- NIH Appendix***  
***Draft for Department of Health and Human Services Review: 6.11.96***

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Awaiting revised appendices from NIH.

## **INTERNATIONAL ACTIVITIES**

**Agency:** Office of International Affairs, Department of Health and Human Services

**Goal:** Support U.S. interests globally by serving as a policy and coordinating body for international activities supported by HHS, a liaison with other U.S. departments and agencies supporting international activities, and a liaison with foreign governments working with U.S.

**Objective:** Improve coordination among HHS and other Federally-supported international activities.

**Action Steps:** Establish and maintain communications with other departments and agencies supporting international activities.

Develop mechanism for tracking HHS-related international activities.

**Descriptions:** International activities mapping project.

**FY 95:** NA - HIV activities integrated into overall budget

**FY 96:** NA - HIV activities integrated into overall budget

**FY 97:**

**Populations Served:** Program planners and policy makers.

**Constituency Involvement:** ????

**Unmet Need:** Staff to initiate and complete project.

## **PREVENTION**

**Agency:** Office of Population Affairs

**Goal:** Reduce the number of new infections.

**Objective:** Provide counseling, education, and HIV testing as needed to Title X program clinics.

**Action Steps:** Include HIV/AIDS education in all clinic education programs.

Include HIV/AIDS prevention in STD screening programs.

Provide HIV testing or referral for testing to all Title X clients who request testing.

**Descriptions:** Title X Program

**FY 95:** NA -- HIV services integrated into overall budget.

**FY 96:** NA -- HIV services integrated into overall budget.

**FY 97:**

**Populations Served:** The Title X program provides family planning and related reproductive health services to approximately 4.5 million clients annually through a network of 4,500 clinics. Clients are predominantly young women; most are members of low-income families, and 30 percent are adolescents and 2/3 are below age 25.

**Constituency Involvement:** For non-profit grantees, clients participate on boards of directors. For all grantees, clients participate on committees approving all information and education materials.

**Unmet Need:** The Title X program reaches an estimated 50 percent of potential clients. Expansion of program would provide a concomitant expansion in HIV/AIDS prevention activities, since these are provided as an integral part of the reproductive health services in Title X programs.

## **CARE AND SERVICES**

**Agency:** Substance Abuse and Mental Health Services Administration

**Goal:** Reduce the rate of HIV transmission among high-risk substance abusers and their sexual partners.

**Objective 1:** To provide a range of high quality mental health services to people affected by or living with HIV/AIDS; change risk behaviors and prevent further HIV transmission; evaluate the effectiveness and efficiency of the different approaches or models used for organizing and providing those services, and determine the outcome of those services on the quality of life of the individuals served.

**Action Steps:** Increase compliance with medical treatment and enhance access to existing services;

Disseminate information about successful service models;

Develop and rigorously evaluate models for replication and integration into HIV/AIDS delivery systems; and

Increase productive work capacity as result of receiving services.

**Descriptions:** HIV/AIDS Mental Health Services Demonstration Program.

**FY 95:** \$1,500,000 (With \$1,400,000 from NIH and \$1,500,000 from HRSA)

**FY 96:** \$1,500,000 (With \$1,400,000 from NIH and \$1,500,000 from HRSA)

**FY 97:**

**Populations Served:** People living with or affected by HIV/AIDS including injection drug users, sex partners of injection drug users, sex workers, gay or bisexual men, and racial and ethnic minority populations.

**Constituency Involvement:** Health professionals, consumers, and community service providers.

**Unmet Need:** This collaborative effort has successfully enhanced the services rendered by providing comprehensive services to the populations served. However, additional financial resources could include other agencies, i.e. HUD, AHCPR in providing the client population with a spectrum of services relating to diverse needs.

**Objective 2:** To demonstrate the efficacy of outreach as an intervention for facilitating access

***The National Strategy for HIV and AIDS -- SAMSHA Appendix  
Draft for Department of Health and Human Services Review: 6.11.96***

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to substance abuse treatment for high risk and hard to reach substance abusers.

To demonstrate that comprehensive HIV outreach interventions affect behavior changes in diverse populations.

**Action Steps:** Identify chronic, hardcore, drug users and their sex and/or needle-sharing partners;

Facilitate entry into substance abuse treatment;

Provide a range of services including medical and diagnostic services for HIV, STDs, and TB;

Employ information-sharing, skills and other prophylactic means to affect behavior change; and

Evaluate program effectiveness.

**Descriptions:** HIV/AIDS Community Outreach Program.

**FY 95:** \$7,500,000

**FY 96:** \$7,500,000

**FY 97:**

**Populations Served:** Chronic, hard core substance abusers and their sex and/or needle-sharing partners, including those individuals who have severe drug problems, frequently inject heroin and/or cocaine and/or are poly drug users. There is also emphasis within various racial and ethnic groups, women, residents of public housing projects, and homeless individuals.

**Constituency Involvement:** Health professionals, consumers, and community service providers.

**Unmet Need:** Additional resources for medical treatment of HIV/AIDS, STDs, TB and other medical services would provide greater access to care through integration of substance abuse and medical care services.

## **CARE AND SERVICES**

**Agency:** Substance Abuse and Mental Health Services Administration

**Goal:** Improve HIV/AIDS training of clinicians.

**Objective 1:** Enhance mental health professionals' prevention and treatment efforts by training mental health care providers and other health care workers.

**Action Steps:** Assess neuropsychiatric/psychosocial aspects of HIV/AIDS to prevent the spread of HIV infection;

Establish linkages with health care providers;

Include alcohol and other drug (AOD) related HIV prevention in all training curriculums;

Train mental health professionals who serve people with serious mental illness;

Provide training about pre and post HIV antibody counseling and testing, physiological aspects of HIV/AIDS, in addition to culturally sensitive, linguistically and gender appropriate interventions and methodologies;

Address managed care and training issues; and

Evaluate the effectiveness of training techniques.

**Descriptions:** AIDS Health Care Worker Training.

**FY 95:** \$2,930,000

**FY 96:** \$2,930,000

**FY 97:**

**Populations Served:** HIV/AIDS mental health care providers whose client population may include gay and bisexual men, women, racial and ethnic minority groups, injecting drug users and their sex partners, sex workers, children, adolescents, and the sex partners of people with HIV/AIDS.

**Constituency Involvement:** Health professionals, consumers, and community service providers.

***The National Strategy for HIV and AIDS -- SAMSHA Appendix  
Draft for Department of Health and Human Services Review: 6.11.96***

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**Unmet Need:** Additional financial resources and increased collaboration with other Federal agencies would broaden the scope of the training to include all health professionals.

**Objective 2:** Provide training programs for health care professionals, modifying curricula and strengthening training opportunities in comprehensive care for people with or at risk for substance abuse, mental illness and infectious diseases including HIV and TB.

**Action Steps:** Train health care professionals to provide comprehensive services and care; and

Enhance curricula by including training for diverse populations with multiple risk factors and illnesses.

**Descriptions:** AIDS Training Grants.

**FY 95:** \$2,800,000

**FY 96:** \$0

**FY 97:**

**Populations Served:** People with or at risk for substance abuse, mental illness and/or transmission of HIV.

**Constituency Involvement:** Health professionals and consumers.

**Unmet Need:** Additional resources would strengthen the training opportunities for health care professionals and enhance services rendered for people with or at risk for substance abuse, mental illness, HIV, and other STDs.

## **CARE AND SERVICES**

**Agency:** Substance Abuse and Mental Health Services Administration

**Goal:** Improve the integration of substance treatment and primary medical care.

**Objective:** To demonstrate the effectiveness of fostering greater services integration by linking substance abuse treatment, primary medical care, mental health services, and HIV/AIDS, STD and TB services.

**Action Steps:** Develop and foster linkages among service providers; and

Evaluate the efficiency and effectiveness of linked, integrated services.

**Descriptions:** The Linkage Initiative.

**FY 95:** \$7,700,000

**FY 96:**

**FY 97:**

**Populations Served:** Injecting drug users and other high risk substance abusers and their sexual partners.

**Constituency Involvement:** Service providers and consumers

**Unmet Need:** This collaborative effort serves as catalyst for linking AOD treatment, mental health and primary care services, and services for HIV/AIDS, STDs and TB. Additional resources could join this effort with other agencies to enhance the services rendered.

## **PREVENTION**

**Agency:** Substance Abuse and Mental Health Services Administration

**Goal:** Reduce the number of new HIV infections.

**Objective 1:** Reduce the number of new infections by 25 percent among clients served by grantees?.

Demonstrate the differential effectiveness of incorporating HIV/AIDS prevention curricula into ongoing substance prevention programs.

**Action Steps:** Supplementation of high risk youth grants for alcohol, tobacco and other drugs (ATOD) prevention for the purpose of including HIV/AIDS prevention strategies in their present activities;

Develop program to empower youth with skills, knowledge, and beliefs for HIV prevention;

Demonstrate effective strategies to prevent ATOD use and abuse among high risk youth; and

Include developmentally and culturally appropriate HIV/AIDS education and prevention approaches.

**Descriptions:** High Risk Youth Program.

**FY 95:** \$1,000,000

**FY 96:** \$3,000,000

**FY 97:**

**Populations Served:** High risk youth or youth at risk for ATOD, adolescent females, and youth at risk for AOD-related violent behavior.

**Constituency Involvement:** Families of youth, youth service workers, and the communities that support youth at risk for ATOD abuse.

**Unmet Need:** Presently this initiative reaches only 25 percent of high risk youth grantees. Supplementing all grantees would provide greater opportunity for services integration and evaluation.

***The National Strategy for HIV and AIDS -- SAMSHA Appendix  
Draft for Department of Health and Human Services Review: 6.11.96***

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**Objective 2:** Apply a community-designed, community-focused approach to the prevention of HIV/AIDS in a culturally appropriate manner, specifically targeting communities of high seroprevalence.

Reduce ATOD use.

**Action Steps:** Supplementation of all community partnerships and community coalitions providing communities with the opportunity to design targeted HIV/AIDS messages emphasizing the direct relationship between the use of ATOD and HIV/AIDS; and

Solicit neighboring communities in program implementation.

**Descriptions:** Demonstration sites and community training in the use of HIV/AIDS curriculum.

**FY 95:** \$0

**FY 96:** \$5,000,000

**FY 97:**

**Populations Served:** American communities. (More information regarding which communities....)

**Constituency Involvement:** All community members.

**Unmet Need:** Supplementing all community coalition grantees and partnerships would provide greater opportunity for services integration and evaluation.

**Objective 3:** Improve training of Faculty Development Program (FDP) grantees.

**Action Steps:** Supplement all FDP grantees for the purpose of improving teaching skills related to integration ATOD and HIV/AIDS prevention; and

Improve training regarding professional/client interaction.

**Descriptions:** Supplementation of Faculty Development Program (FDP) grantees.

**FY 95:** \$0

**FY 96:** \$650,000

**FY 97:**

***The National Strategy for HIV and AIDS -- SAMSHA Appendix  
Draft for Department of Health and Human Services Review: 6.11.96***

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**Populations Served:** General public.

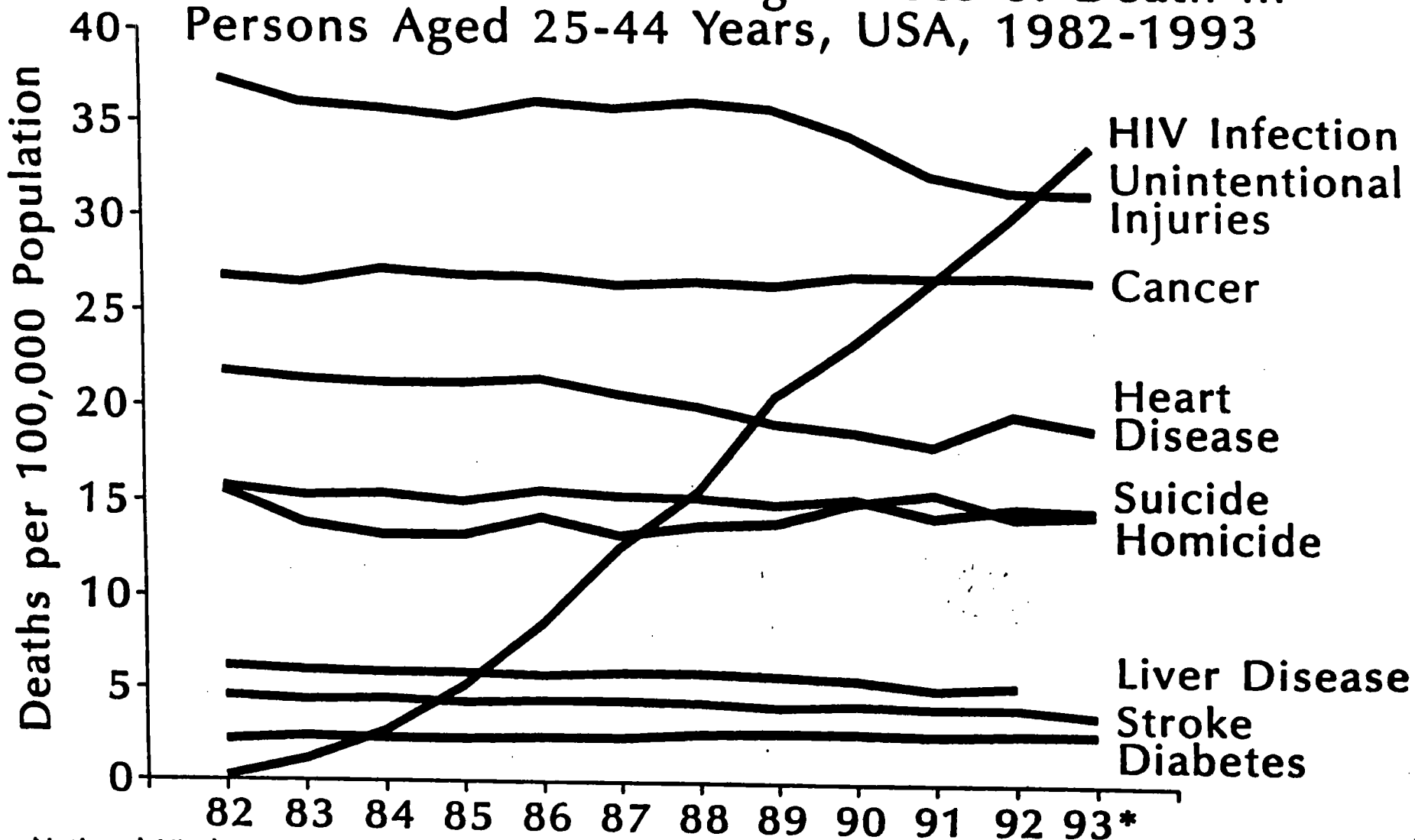
**Constituency Involvement:** Health professional institutions, consumers, and community service providers.

**Unmet Need:** Additional resources could provide further education and training and thereby reach more health professionals.

***IV. FIGURES, ACRONYMS, AND MEMBERS OF THE INTERDEPARTMENTAL TASK  
FORCE ON HIV AND AIDS***

***Figure 1***      Death Rates from Leading Causes of Death in Persons Aged 25-44 Years,  
USA, 1982 -1993

# Death Rates from Leading Causes of Death in Persons Aged 25-44 Years, USA, 1982-1993



National Vital Statistics

\*Provisional data



***The National Strategy for HIV and AIDS***  
***Draft for Department of Health and Human Services Review: 6.11.96***

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***Figure 2*** Cumulative U.S. AIDS Cases: 2/83 through 12/94

# Cumulative U.S. AIDS Cases as of 2/83 N~1,000

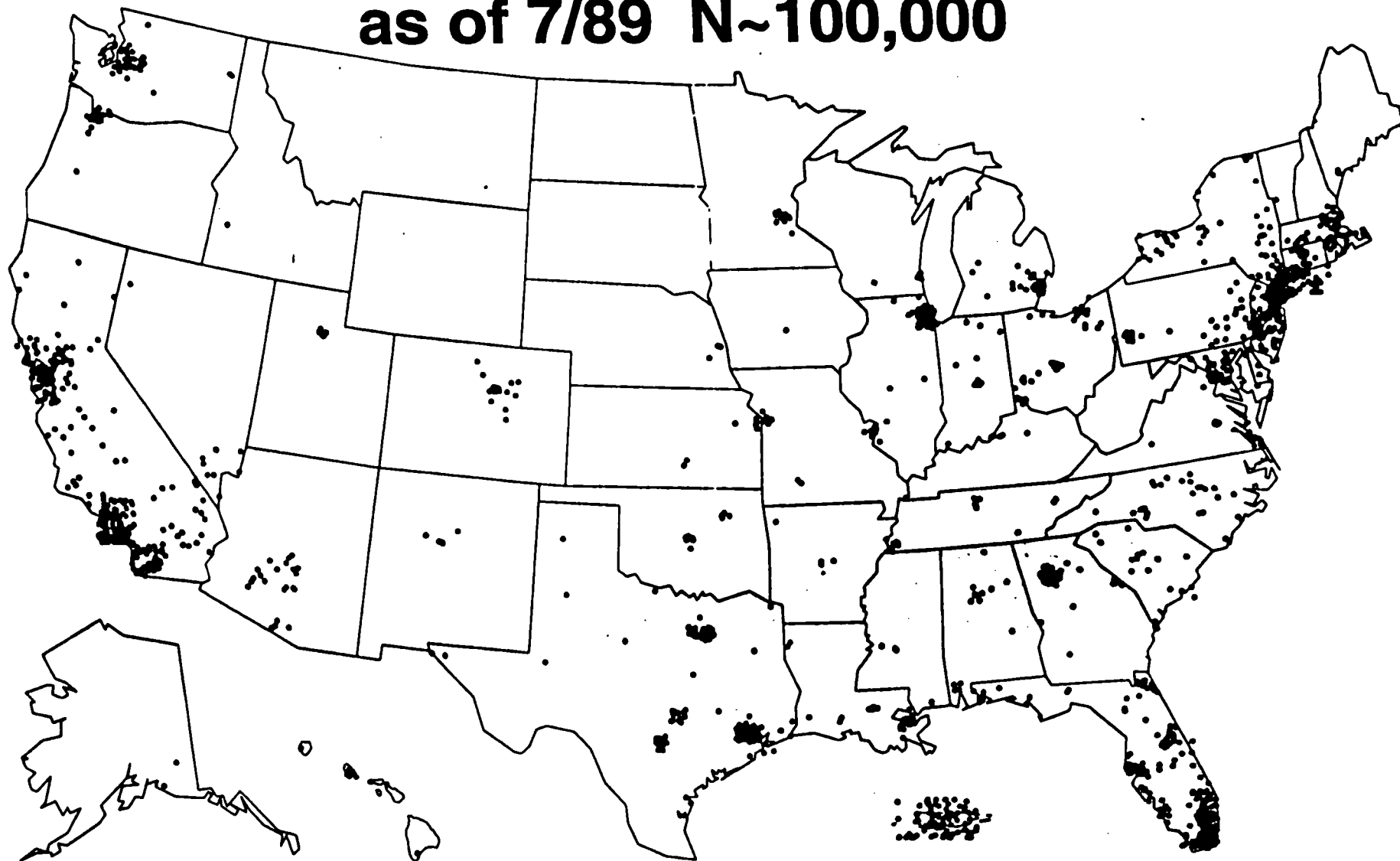


# **Cumulative U. S. AIDS Cases as of 5/85 N~10,000**

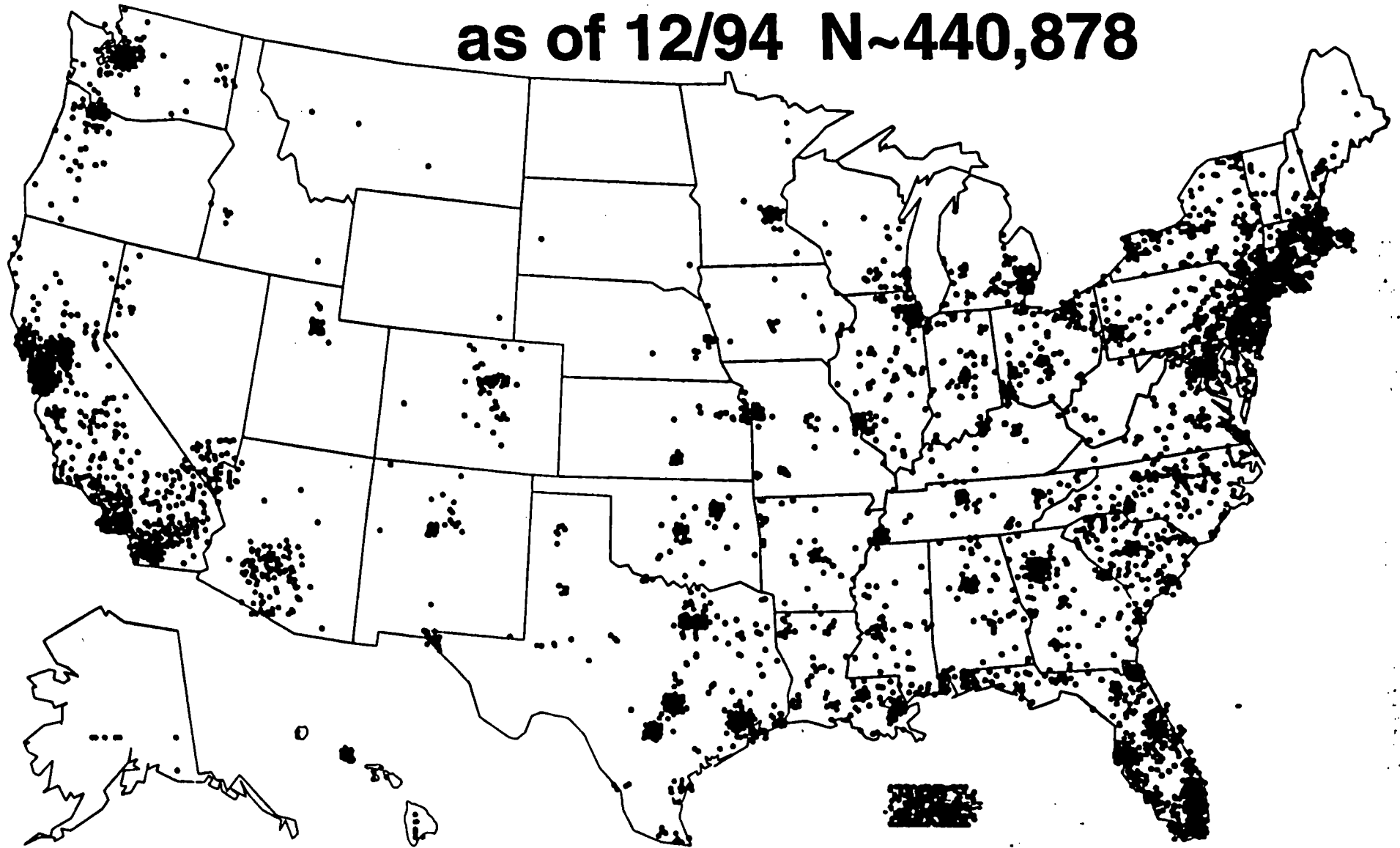


**Each point = 30 cases**

# **Cumulative U.S. AIDS Cases as of 7/89 N~100,000**



# **Cumulative U. S. AIDS Cases as of 12/94 N~440,878**



**Each point = 30 cases**

***The National Strategy for HIV and AIDS***  
***Draft for Department of Health and Human Services Review: 6.11.96***

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***Acronym List***

|       |                                                                  |
|-------|------------------------------------------------------------------|
| ACTG  | AIDS Clinical Trial Group                                        |
| ADA   | Americans with Disabilities Act of 1990                          |
| ADC   | AIDS Dementia Complex                                            |
| ACTIS | AIDS Clinical Trials Information Service                         |
| ADAP  | AIDS Drug Assistance Programs                                    |
| AETC  | AIDS Education Training Center                                   |
| AHCPR | Agency for Health Care Policy and Research                       |
| AIDS  | Acquired Immune Deficiency Syndrome                              |
| AOD   | Alcohol and other drugs                                          |
| ASO   | AIDS Service Organization                                        |
| ATIS  | HIV/AIDS Treatment Information Service                           |
| ATOD  | Alcohol, tobacco, and other drugs                                |
| AZT   |                                                                  |
|       |                                                                  |
| BOP   | Bureau of Prisons                                                |
| BRTA  | Business Responds to AIDS                                        |
|       |                                                                  |
| CARE  | Ryan White Comprehensive AIDS Resources Emergency Act            |
| CDBG  | Community Development Block Grant                                |
| CDC   | The Centers for Disease Control and Prevention                   |
| CMV   | Cytomegalovirus                                                  |
| CNS   | Central Nervous System                                           |
| CPCRA | Terry Bein Community Programs for Clinical Research on AIDS      |
|       |                                                                  |
| DEA   | Drug Enforcement Agency                                          |
| DHHS  | Department of Health and Human Services                          |
| DOD   | Department of Defense                                            |
| DOJ   | Department of Justice                                            |
| DOL   | Department of Labor                                              |
|       |                                                                  |
| EDC   | Educational Development Center                                   |
| EEOC  | Equal Employment Opportunity Commission                          |
| ENFPA |                                                                  |
|       |                                                                  |
| FDA   | Food and Drug Administration                                     |
| FBI   | Federal Bureau of Investigation                                  |
|       |                                                                  |
| GCRC  | General Clinical Research Centers Program                        |
| GIPA  | Greater Involvement of Persons Infected and Affected by HIV/AIDS |

***The National Strategy for HIV and AIDS***

***Draft for Department of Health and Human Services Review: 6.11.96***

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|       |                                                              |
|-------|--------------------------------------------------------------|
| HCFA  | Health Care Financing Administration                         |
| HIV   | Human Immunodeficiency Virus                                 |
| HOPWA | Housing Opportunities for Persons with AIDS                  |
| HRSA  | Health Resources and Services Administration                 |
| HSV   | Herpes Simplex Virus                                         |
| HUD   | Department of Housing and Urban Development                  |
| ICD   | Institute(s), Center(s), Division(s)                         |
| IDTF  | Interdepartmental Task Force on HIV and AIDS                 |
| IHS   | Indian Health Service                                        |
| INS   | Immigration and Naturalization Service                       |
| IOM   | Institute of Medicine                                        |
| JMD   | Justice Management Division                                  |
| LRTA  | Labor Responds to AIDS                                       |
| MAC   | <i>Mycobacterium Avium</i> Complex                           |
| NCRR  | National Center for Research Resources                       |
| NGO   | Non-governmental Organization                                |
| NIDA  | National Institute on Drug Abuse                             |
| NIH   | National Institutes of Health                                |
| NREN  | National Research and Education Network                      |
| NVC   | National Victims Center                                      |
| OAR   | Office of AIDS Research                                      |
| OI    | Opportunistic Infection                                      |
| OMB   | Office of Management and Budget                              |
| ONAP  | Office of National AIDS Policy                               |
| PAC   | Presidential Advisory Council on HIV and AIDS                |
| PCP   | <i>Pneumocystis carinii</i> pneumonia                        |
| PHS   | Public Health Service                                        |
| PLWH  | Persons living with HIV                                      |
| PSA   | Public Service Announcement                                  |
| PVO   | Private Voluntary Organization                               |
| PWA   | Person with AIDS                                             |
| RFIP  | Research Facilities Infrastructure Program (NIH)             |
| RPRC  | Regional Primate Research Center (NIH)                       |
| RWCA  | Ryan White Comprehensive AIDS Resources Emergency (CARE) Act |

***The National Strategy for HIV and AIDS***  
***Draft for Department of Health and Human Services Review: 6.11.96***

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|               |                                                                  |
|---------------|------------------------------------------------------------------|
| <b>SAMHSA</b> | <b>Substance Abuse and Mental Health Services Administration</b> |
| <b>SPF</b>    | <b>Specific Pathogen-Free</b>                                    |
| <b>SPNS</b>   | <b>Special Projects of National Significance</b>                 |
| <b>SSA</b>    | <b>Social Security Administration</b>                            |
| <b>SSI</b>    | <b>Supplemental Security Income</b>                              |
| <b>STD</b>    | <b>Sexually transmitted disease</b>                              |
| <b>STI</b>    | <b>Sexually transmitted infection</b>                            |
| <b>TA</b>     | <b>Technical Assistance</b>                                      |
| <b>TB</b>     | <b><i>Mycobacterium tuberculosis</i></b>                         |
| <b>UNAIDS</b> | <b>United Nations Programme on AIDS</b>                          |
| <b>UNDP</b>   |                                                                  |
| <b>UNICEF</b> |                                                                  |
| <b>USAID</b>  | <b>U.S. Agency for International Development</b>                 |
| <b>USIA</b>   | <b>U.S. Information Agency</b>                                   |
| <b>USMS</b>   | <b>U.S. Marshals Service</b>                                     |
| <b>VA</b>     | <b>Department of Veterans Affairs</b>                            |
| <b>WHO</b>    | <b>World Health Organization</b>                                 |

## TABLE OF CONTENTS

### MESSAGE FROM THE DIRECTOR OF THE OFFICE OF NATIONAL AIDS POLICY

#### PREFACE

The Need for a National Strategy for HIV and AIDS  
The Strategy as a Catalyst for Change

*Pandemic  
Public Health Threat  
Impact  
of the HIV/AIDS Epidemic  
Strategy  
the Strategy  
ives and Opportunities for Progress  
the Strategy  
EFFORTS*

*into Practice*

evention, Research, Care and Services, International  
tivities, Translation of Research into Practice, Civil  
rights)

Appendix G

Budget Tables

#### IV. FIGURES, ACRONYMS, AND MEMBERS OF THE INTERDEPARTMENTAL TASK FORCE ON HIV AND AIDS

Figure 1

Death Rates from Leading Causes of Death in  
Persons Aged 25-44 Years, USA, 1982 -1993

7.19

Richard -

Here's another  
copy of the plan  
I gave you on 6.14

Thanks for your  
help.

June

June 12, 1996

**MEMORANDUM FOR THE INTERDEPARTMENTAL TASK FORCE ON HIV AND AIDS,  
OFFICE OF NATIONAL DRUG CONTROL POLICY**

**FROM:** Patricia S. Fleming  
Director, Office of National AIDS Policy

**SUBJECT:** Review of Draft of the National Strategy for HIV and AIDS

As a result of our meetings last year each member of the Interdepartmental Task Force on HIV/AIDS (IDTF) was asked to develop individual department and agency plans for HIV/AIDS, linking goals and objectives to budget levels and identifying areas of unmet need.

The individual plans you submitted were carefully studied. This past February, IDTF members reviewed the draft and provided comment. We are in the final stages of revising the document as informed by this review, and, updating budget figures.

Attached is the revised draft of the National Strategy for HIV and AIDS. Please review the attached draft and your appendix carefully. You should:

- Update the budget table to reflect current figures, noting FY 95 actuals, FY 96 estimates, and the FY 97 President's budget request for each agency goal. (These budget figures will be cross-checked with OMB figures.) The attached table reflects the budget levels provided in your revised submission.
- Information that was missing or unclear has been 'redlined'. Please be certain to provide this information.
- Check for the accuracy of department and agency names, program titles, and acronyms.
- Make sure that your comments are clear and specific. Comments are due back to the Office of National AIDS Policy **BY NO LATER THAN JUNE 21, 1996**. If you have any questions please call Jane Sanville at (202) 632-1090.

Thank you for your assistance in developing this first-ever National Strategy for HIV and AIDS.

**Attachments:**

The National Strategy for HIV and AIDS, 6.11.96 draft

ONDCP Appendix for The National Strategy for HIV and AIDS, 6.11.96 draft

**PAGE 2: MEMORANDUM FOR THE INTERDEPARTMENTAL TASK FORCE ON  
HIV AND AIDS, OFFICE OF NATIONAL DRUG CONTROL POLICY**

| Area       | Objective                                                                                                    | FY 95<br>Actuals | FY 96<br>Estimate | FY 97 President's<br>Budget |
|------------|--------------------------------------------------------------------------------------------------------------|------------------|-------------------|-----------------------------|
| Treatment  | Reduce the number of injection drug use and cocaine addicts with high risk sex practices 20 percent by 1997. | \$1,600,000      | \$1,600,000       |                             |
| Prevention | Reduce the number of injection drug use and cocaine addicts with high risk sex practices 20 percent by 1997. | \$1,600,000      | \$1,600,000       |                             |

## **TABLE OF CONTENTS**

### ***MESSAGE FROM THE DIRECTOR OF THE OFFICE OF NATIONAL AIDS POLICY***

#### ***PREFACE***

**The Need for a National Strategy for HIV and AIDS**  
**The Strategy as a Catalyst for Change**

#### ***I. INTRODUCTION***

***Scope of the HIV/AIDS Pandemic***  
**An Expanding Public Health Threat**  
**The Social Impact**

***The Evolving Challenge of the HIV/AIDS Epidemic***

***Goal of the National Strategy***  
**Development of the Strategy**  
**Common Objectives and Opportunities for Progress**  
**Implementation**  
**Organization of the Strategy**

#### ***II. OVERVIEW OF FEDERAL EFFORTS***

***Introduction***  
***Prevention***  
***Research***  
***Care and Services***  
***International Activities***  
***Translation of Research into Practice***  
***Civil Rights***

#### ***III. APPENDICES***

***Appendices A - F*** (Prevention, Research, Care and Services, International Activities, Translation of Research into Practice, Civil Rights)

***Appendix G*** Budget Tables

#### ***IV. FIGURES, ACRONYMS, AND MEMBERS OF THE INTERDEPARTMENTAL TASK FORCE ON HIV AND AIDS***

***Figure 1*** Death Rates from Leading Causes of Death in Persons Aged 25-44 Years, USA, 1982 -1993

***The National Strategy for HIV and AIDS***

***Draft for Office of National Drug Control Policy Review: 6.11.96***

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***Figure 2***

Cumulative U.S. AIDS Cases: 2/83 through 12/94

***Acronym List***

***Members of the Interdepartmental Task Force on HIV and AIDS***

***Message from the Director of the  
Office of National AIDS Policy***

The epidemic of HIV and AIDS constitutes a public health crisis of unprecedented proportions. In 1993, the Office of National AIDS Policy (ONAP) was created by President Clinton to provide a national focus and direction for the government's response to HIV and AIDS. More recently, President Clinton asked ONAP to develop a comprehensive National Strategy that would chart the Administration's direction in responding to the HIV/AIDS national and international pandemic. This was as a result of the President's commitment to promote efficient and collaborative policy and program efforts.

The development of a National Strategy for HIV and AIDS is an historic undertaking. No previous administration has undertaken so broad a planning effort that: (1) involves all Federal Departments and Agencies that engage in HIV-related efforts; (2) reaches out to communities and the private sector; and, (3) identifies areas where the Nation should place its most concerted efforts.

Combating HIV disease will require nothing less than the best innovative and cooperative efforts of State, local and federal governments, the private sector, and infected and affected communities and individuals. The urgency of the crisis requires that we build upon what we have already learned, joining together with one

another to develop a new, more unified and collaborative approach to addressing the epidemic.

The Strategy was developed through consultation with, and guidance from, many groups and individuals. I would like to thank, in particular, the members of the Interdepartmental Task Force on HIV and AIDS (IDTF) for the time and attention that they, and their staffs, contributed to the development of the Strategy. The IDTF is a group consisting of representatives from executive branch Departments and Agencies that conduct HIV-relevant work.

In developing the document, we depended heavily upon groups outside of government as well -- they, too, have been, and will continue to be, essential partners in developing solutions that capitalize on the opportunities for progress that are now before us. The recommendations provided by the Presidential Advisory Council on HIV and AIDS (PAC), the advocacy community, participants in the White House Conference on HIV and AIDS, service providers on the front lines of the epidemic, and many HIV-positive persons, their families, friends and care givers have been central to identifying areas for focused attention. The insights provided by the National Commission on AIDS, the Institute of Medicine and National Research Council, the General Accounting Office, and the reports of the Office of Technology Assessment have also been extraordinarily helpful in developing the National Strategy.

*The National Strategy for HIV and AIDS*  
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This document is a snapshot of where we are and where we think we need to go. Collaboration is one of the hallmarks of this Administration's approach to AIDS policy and Strategy serves as a reference point for lengthier dialogues and collaborative efforts between the public and private sectors.

It is important to remember that our efforts would not have been possible without leadership and direction at the highest levels of government. While the challenges of HIV/AIDS that are facing us cannot be solved by government or the private sector acting alone, more than ever in the history of this epidemic, we need innovative ideas, careful planning, and the strength of public-private partnerships to bring our strategy to fruition.

The epidemic challenges us on many fronts. Because the most common transmission routes are sexual activity and drug use, topics difficult for many Americans to confront directly, HIV has challenged this country to look at things that are difficult to face.

There is also fear -- fear of contracting this disease and unwarranted fear of those who are infected. Fifteen years into the epidemic, persons living with HIV still endure daily prejudice and discrimination based upon their HIV status. We are further challenged by the inadequacies of a social and health care infrastructure that is, in many ways, woefully unprepared to address the needs of HIV-infected persons. Moreover, the safety net provided by programs such as Medicaid and Medicare is

threatened with fundamental programmatic changes and reductions in funding. Scientifically, we have made much progress, but the virus continues to be a formidable adversary, challenging the best and brightest among us to find a cure and a vaccine.

Despite the many difficulties, AIDS has also brought forth an outpouring of compassion and caring. In my many meetings around the country with persons living with HIV, I have been inspired by numerous examples of great personal courage. I have been impressed by the dedication with which many communities and individuals have overcome obstacles in preventing infections and caring for those who are sick. By example, it demonstrates that, as a Nation, we, too, can collectively rise to meet the most difficult challenges placed in our path. Those Americans living with HIV, and others who are at-risk of infection, their families, and their communities, deserve a thoughtful, effective, and aggressive strategy to combat the disease.

Today we are facing great challenges, but we are also facing equally great opportunities. While AIDS is a terrible tragedy that has already affected far too many people around the world, I believe it is a disease that we can defeat -- just as we have eradicated polio from the western hemisphere and smallpox from the world. The National Strategy for HIV and AIDS lays a foundation for the public-private partnerships that are essential to our success. Together, with steadfast commitment, courage, and leadership, we will be able to win the battle against HIV and AIDS.

## ***Preface***

### **The Need for a National Strategy for HIV and AIDS**

The National Strategy for HIV and AIDS has been developed to capitalize upon progress already made in fighting the epidemic and to catalyze collaborative efforts among Federal Departments and Agencies, communities, State and local governments, and the private sector.

Since the discovery of the first AIDS cases in the early 1980s, the epidemic of HIV and AIDS has posed a series of unique challenges. The challenges today are very different from those that we faced ten or even five years ago. We now know the risk factors and the etiologic agent, and we have tests to diagnose infection and protect the blood supply. We are developing new and more powerful therapies that offer hope for treatment and prevention. Scientists now believe that a vaccine is possible. Nonetheless, the epidemic continues. More people are infected every year, in every geographic area, and in every age range. Racial and ethnic minorities are disproportionately represented among existing and new cases of HIV infection. And youth are at increasing risk. Internationally, the epidemic is threatening the economic stability of a number of developing nations.

The changing face of HIV and AIDS, coupled with a period of overall fiscal restraint and a trend toward managed health care programs, require new approaches and

solutions. The National Strategy must incorporate innovative ideas, careful planning, and the strength of public-private partnerships.

### **The Strategy as a Catalyst for Change**

The National Strategy is intended to serve the public, the President, the Congress, the members of the Interdepartmental Task Force on HIV/AIDS, and Presidential Advisory Council on HIV and AIDS. The text that follows will serve as a blueprint that will: document the baseline of current efforts government-wide; link goals to budget objectives; and, guide us in refining our goals and objectives in response to the changing face of the epidemic of HIV and AIDS.

The Strategy does not prescribe a fixed sequence of steps by which the entire plan, and its identified opportunities, are to be accomplished. The goals, common objectives, and opportunities for progress are intended to serve as a focus for our attention and efforts. The development of a functional implementation plan will be the responsibility of the Office of National AIDS Policy in partnership with the Interdepartmental Task Force on HIV/AIDS, the Presidential Advisory Council on HIV and AIDS, private sector organizations, and the community.

***Executive Summary***

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## **I. INTRODUCTION**

### ***Scope of the HIV/AIDS Pandemic***

The pandemic of Human Immunodeficiency Virus (HIV) and Acquired Immunodeficiency Syndrome (AIDS) presents unique social, economic, and public health challenges to governments and individuals here in the United States and worldwide. Unlike other infectious diseases that have arisen over the course of history, HIV is infectious for life and almost always fatal. [Awaiting revised language from NIH.] While we have made significant progress in understanding the disease and developing treatments since the first case was identified by the CDC in June of 1981, with this progress comes the challenge of preventing new infections, ensuring access to new treatments, and assuring that health care professionals know how to care for their patients. Still, HIV remains a deadly infection for which there is no vaccine, no cure, and for which there is an expanding, but still limited, inventory of available treatments.

### **An Expanding Public Health Threat**

As of October 1995, the Centers for Disease Control and Prevention (CDC) reported 501,310 cases of AIDS among persons in the U.S.; 311,381 of these persons have been reported to have died as a result of complications related to HIV. Since 1987, AIDS has gone from being the 15th ranked cause of death among all Americans to the 8th. It is now the leading cause of death among Americans aged 25 to 44. (See

Figure 1.) In 1994 alone, approximately 81,000 new cases of AIDS and more than 45,000 AIDS-related deaths were reported to the CDC in 1994. The CDC estimates that between 40,000 and 60,000 Americans are becoming newly infected with HIV each year, and that between 800,000 and one million Americans are currently living with HIV.

As the epidemic in the United States has evolved, the demographics of the epidemic have been shifting. The early years of the epidemic were dominated by cases involving gay or bisexual men living in major urban centers, such as New York, San Francisco, and Los Angeles; this group now represents less than half of all new cases. Among the populations being more heavily affected now are young gay men, women, and heterosexual injecting drug users. Although gay men no longer represent the majority of new cases, this groups represents the majority of persons living with HIV and AIDS. In 1994, more than 14,000 women were reported with AIDS and now women comprise 14 percent of cumulatively reported AIDS cases. It is estimated that if this trend continues, 80,000 American children will have been orphaned as a result of AIDS by the end of this decade. In 1994 alone, more than 1,000 new pediatric AIDS cases were reported. As the geographic diversity of the disease has widened, the impact of the disease on the country as a whole has increased.

Adolescents are at special risk. The CDC estimates that one in four new HIV infections in the U.S. occur among people

under the age of 21. Under current trends, between 27 and 54 young people in the United States under the age of 21 are infected by HIV each day, or more than two young people every hour. Moreover, a significant number of young people are engaging in sexual intercourse as well as drug and alcohol use at earlier stages in their lives. This fact, coupled with the disturbing number of adolescents who are prone to high risk behavior due to homelessness, sexual abuse, and other circumstances, places young Americans in a situation that leaves them extremely vulnerable to HIV infection.

Communities of color have been more severely and disproportionately affected by the epidemic. As of October 1995, African-Americans accounted for 38 percent of newly reported AIDS cases, while representing approximately 12 percent of the general population. Hispanics represented 18 percent of new cases through October 1995, although this group represents only 9 percent of the general population. In 1982, Blacks and Hispanics represented 31 percent of all AIDS cases; however, as of October 1995 these groups comprised 51 percent of cumulative AIDS cases. Gay men of color in certain regions of the country account for approximately 39 percent of new AIDS cases.

AIDS is no longer just an urban problem. The HIV/AIDS pandemic is spreading to non-urban areas, including dramatic increases in certain regions of the South and Midwest. In fact, between 1993 and 1995 the largest numbers of AIDS cases (86,462)

were reported from the South.<sup>1</sup> While most cases are still reported from urban areas, the rate of reported cases in non-metropolitan areas is increasing faster than in urban areas. AIDS cases have now been reported in all 50 States, the District of Columbia, Puerto Rico, and each of the American Territories. (See Figure 2.)

Internationally, the toll of the epidemic is greater still. The World Health Organization (WHO) estimates that since the beginning of the epidemic, 4.5 million cases of AIDS have occurred worldwide. It has estimated that as of mid-1995, 18.5 million adults and more than 1.5 million children have been infected with HIV since the beginning of the pandemic. WHO also projects that by the year 2000 between 30-40 million people will have been infected with HIV.

### **The Social Impact**

Prejudice and discrimination are still experienced by people living with HIV, their families, and their loved ones. Persons with HIV have been denied medical and dental services, emergency medical treatment, and health insurance. They have been discharged from their jobs and evicted from their homes. Unlike other persons with infectious diseases, many persons living with HIV have been the target of violence, rejected by their families, and suffered discrimination because of their HIV status.

AIDS is a disease that most often affects people in the prime of life. It

*The National Strategy for HIV and AIDS*  
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disproportionately kills people during their most productive years. That it is the leading cause of death among Americans 25 to 44 is particularly significant since this is the age group that constituted 54% of the civilian labor force in 1992.<sup>2</sup> Premature deaths due to AIDS result in the loss of many productive years of life and in many cases deprive young children of their parents. In 1994, HIV infection was the fourth leading cause of potential life lost before age 65.

The human toll has been staggering and is likely to continue.

AIDS has consistently risen in the rankings as a cause of death, while rates for disease such as cancer and heart disease have been comparatively stable. Direct lifetime medical care after diagnosis for an HIV-infected person costs more than care for patients with cancer or heart disease, specifically: \$61,211 for heart disease<sup>3</sup>, \$25,000 to 84,000 for Cancer<sup>4</sup>, and \$119,000 for HIV/AIDS<sup>5</sup>. Overall HHS spending for research, treatment, prevention, and income supplements is significantly greater for cancer and heart disease than for AIDS. In FY 1995 DHHS spent approximately: \$38.0 billion for heart disease, \$17.5 billion for cancer, and \$6.0 billion for AIDS. [DHHS -- update figures.]

In developing countries, the pandemic threatens to reverse decades of progress in strengthening national economies and improving the health status and social well-being of millions of women, men, and children. In some African nations, 95 percent of hospital beds are occupied by AIDS patients. Moreover, the WHO estimates that 10 to 15 million children will be orphaned due to AIDS by the year 2000.

***The Evolving Challenge of the HIV/AIDS Epidemic***

The four decades prior to the report of the first AIDS case in the early 1980s encompassed a period of unprecedented success in controlling infectious diseases. The emergence of HIV, and the subsequent epidemic of HIV and AIDS, has posed an evolving series of unique scientific, economic, and social challenges, both domestic and international. Today the challenges we face with the epidemic are very different from challenges we faced previously.

In the early years of the epidemic, significant scientific resources were dedicated towards understanding how the disease was transmitted and identifying its underlying cause. Thanks to this work, we now know the risk factors and the etiologic agent for HIV, and we have a test to ascertain the serostatus of infected persons and can, therefore, protect the blood supply.

Building on the knowledge gained from those discoveries, more resources were subsequently directed towards achieving a deeper understanding of HIV-related immunology and pathogenesis, and, developing therapies for HIV primary infection and associated opportunistic infections. New and more powerful therapies that offer new hope for treatment and prevention have been developed. Scientists now believe that a vaccine is possible. Current day discoveries also create new challenges for the future. We

now face new scientific challenges in developing a vaccine and the new generation of therapeutics for primary and opportunistic infections.

Since the beginning of the epidemic, behavioral research designed to understand the behavioral, social, cognitive, and biological factors that place individuals at risk for acquiring HIV infection has provided important insights for prevention efforts. Practical experience has also taught us that prevention efforts can be effective. However, behavioral research remains a relatively young science and there are currently more questions than answers. The challenge before us now lies in expanding the scientific underpinnings that will allow us to design more effective prevention programs that will reach even more Americans at risk for infection.

The progress in developing therapies and prevention programs has also created new problems for the health care delivery system. As a result of improved therapies, people with AIDS now live twice as long as they did a decade ago. [Awaiting additional language from NIH.] Due to NIH-sponsored research we now have the ability to reduce the risk of perinatally acquired HIV infection by treating women with AZT during pregnancy. The recent approval of a new class of therapies, protease inhibitors, will again change the direction of HIV/AIDS treatment and prevention. Ensuring access to these therapies is the challenge that confronts us now. We need to improve our efforts in providing people with care earlier in their infection so they can receive the

new treatments and we need, as well, to ensure that health care professionals are well-trained and know the best way to provide that care.

Ensuring access to prevention services and medical care for the growing number of people who need, or will need, health care is an enormous task. There are societal and economic changes that are influencing the ways in which the country addresses the issues of health care access and cost. There is a trend towards decentralizing the role of the Federal government in health care and placing more responsibility at the State and local levels, coupled with a movement to managed care systems. These changes will influence efforts to strengthen prevention efforts and ensure health care and services for people with HIV/AIDS.

From a societal perspective, while we have made tremendous progress in overcoming fear and discrimination, we still have a long way to go. There are no grounds for discriminating against persons with HIV infection and yet such action has thwarted access to health care, health insurance, housing, employment, and even funeral services. We must continue in our vigilance to ensure that the protections provided under the law are extended to all HIV-infected persons.

## ***Goal of the National Strategy***

The goal of the National Strategy for HIV and AIDS is to capitalize upon the progress which has been made in fighting the epidemic and to catalyze new and strengthened collaborative efforts among Federal Departments and Agencies, communities, State and local governments, and the private sector. To realize this ambition we will need innovative ideas, careful planning, and the strength of public-private partnerships to make these plans a reality.

The text that follows will serve as a blueprint that will: document the baseline of current efforts government-wide; link goals to budget objectives; and, guide us in refining our goals and objectives in response to the changing face of the epidemic of HIV and AIDS. This is intended to be a living document that will require regular updating and adjustment as goals are reached and as new challenges occur.

## **Development of the Strategy**

The National Strategy for HIV and AIDS presented here is broader in scope than any prior planning efforts. To date, planning has been focused primarily in the Public Health Service (PHS)<sup>6</sup>, Department of Health and Human Services, as evidenced by a series of documents such as the Public Health Service Plan for the Prevention and Control of Acquired Immune Deficiency Syndrome<sup>7</sup>, the "Coolfont"<sup>8</sup> and "Charlottesville"<sup>9</sup> reports, and the PHS Strategic Plan to Combat HIV and AIDS in

the United States<sup>10</sup>. Recommendations have also been issued by a number of groups, including the National Commission on AIDS<sup>11</sup> and the Presidential Advisory Council for HIV and AIDS. There have also been significant planning efforts on the part of individual Agencies. However, until now there has not been a national plan that provides for a government-wide coordinated effort encompassing not just Public Health Service activities, but also that incorporates areas such as housing, health care, and civil rights.

Effective planning requires a genuine commitment from participants to work together toward clearly defined goals. Therefore, the strategy for HIV and AIDS has been developed by the Federal Departments and Agencies that support HIV-related activities along with the counsel of HIV-infected persons and their advocates, the private sector, and the Presidential Advisory Council on HIV and AIDS.

Through the Interdepartmental Task Force on HIV and AIDS (IDTF), a formal request went out for the executive branch Agencies to identify their activities, goals, and objectives. These pertinent data have been compiled uniformly and are contained within the appendices of the strategy. The IDTF members, with their specialized knowledge of a broad range of HIV-related issues, have been crucial in identifying areas requiring special attention.

There has also been a reliance on groups outside of government -- the same groups that have been and will continue to be

essential partners in developing solutions and capitalizing on the opportunities for progress that lay before us now. The recommendations provided by the Presidential Advisory Council on HIV and AIDS (PAC) have been invaluable. The advice and counsel of the activist and advocacy communities, participants in the White House Conference on HIV and AIDS, individuals on the front lines of the epidemic, and many HIV-infected persons and their families, friends, and care givers have been essential in identifying areas for focused attention. And finally, the insights provided by the National Commission on AIDS, the Institute of Medicine of the National Research Council, the General Accounting Office, and the reports of the Office of Technology Assessment have also been extraordinarily helpful in developing this Strategy.

### **Common Objectives and Opportunities for Progress**

Based on the consultations, the following national objectives are established:

- To provide strong support for research in order to find treatments and a cure for those currently infected, and a preventive vaccine to protect the uninfected;
- To provide solid support for effective prevention strategies so as to reduce the number of new infections each and every year until there are no new infections; and,
- To ensure that treatment of persons living with HIV is caring, ethical, and in accordance with legal standards.

Also through the consultations, it became clear that there was consensus regarding the major challenges facing us today, and that these challenges warranted focused attention. There was also a judgment that these challenges represent opportunities for progress -- opportunities to take steps today to find a cure and a vaccine, reduce the number of new infections, and care for those who are infected.

Based on this counsel, opportunities for progress are presented and discussed within each substantive section (i.e., prevention, research, care and services, international activities, translation of research into clinical practice, and civil rights) of the Strategy.

(See section on Organization of the Strategy below.) It is these opportunities that will require consideration and broad-based input in the development of implementation plans if we are to meet the challenges they present.

### **Implementation**

First, it is important to realize that this document is a snapshot of where we are and where we think we need to go. The Strategy serves as a reference point for the lengthier dialogues and a foundation for future collaborative planning efforts between the public (i.e., Federal, State, and local governments), and private (i.e., persons living with HIV, AIDS service organizations, the advocacy and activist community, businesses, pharmaceutical and biotechnology companies, academia, health care providers, and insurers, etc.) sectors that will be absolutely essential.

Each issue raised in the Strategy will require specially tailored approaches and implementation plans. In some cases significant progress has already been made, in others much work remains. Some of these challenges can be resolved with the cooperation of a handful of people, while others will require extensive thoughtful effort on the part of many players in order to craft workable solutions. It will also be important to build on the less comprehensive planning efforts that have taken place and complement current planning activities.

### **Organization of the Strategy**

The National Strategy is organized into the following substantive areas: prevention, research, care and services, international activities, translation of research into practice, and civil rights.

Information and discussion of Federal activities can be found in three locations within the document. First, discussion on each substantive area addresses broad policy issues and new Federal objectives in terms of the national goals and opportunities for progress. Second, each substantive section has a corresponding appendix that provides information on individual Agency goals, objectives, funding levels, constituency involvement, and unmet needs. And third, funding tables can be found in Appendix G.

Current Agency activities have not been arranged around administrative structures, but by area. In cases where a single Agency may have responsibility for more than one area, such as prevention and research, documentation of their activities will be found in the respective substantive sections. In some cases there are cross-cutting issues that could fall into several categories, such as internationally-based treatment and prevention efforts. In this case, programs that are specifically targeted towards geographic regions of the world are included in the international section.

The type of information provided in the appendices varies depending upon the type of efforts Departments and Agencies sponsor. Support for HIV/AIDS activities

falls into two general categories: in the first, HIV/AIDS activities are an essential part of the mission; in the second category, HIV-related activities are not an explicit part of the mission but are indirectly supported or receive collateral benefit from Agency supported work and/or policies. There are a number of Agencies for whom AIDS-specific activities are central to their mission (e.g., the National Institutes of Health (NIH), the Centers for Disease Control and Prevention (CDC), and the Health Resources and Services Administration (HRSA)), while other Agencies maintain programs and activities that support a broad range of activities, of which HIV-related activities are one among many (e.g., the U.S. Agency for International Development (USAID) and the Department of Justice (DOJ)). Data are presented, therefore, in a manner consistent with an Agency's level of involvement.

## **II. OVERVIEW OF FEDERAL EFFORTS**

### ***Introduction***

The scope and nature of the HIV/AIDS epidemic have brought State, local, and Federal involvement into many HIV-related activities. The Federal government, through its public health responsibilities in such areas as research, prevention, health care, and housing has seen a dramatic increase in its activities since the beginning of the epidemic. In 1985 the Federal government spent \$212 million for AIDS research, surveillance, and care. With the dramatic increase in cases, by 1995 that figure had reached \$6,848 million. (See Appendix G). Congress also took note of the rapid increase in cases of HIV and AIDS and passed legislation that sought to address the needs of HIV-infected persons and their families, and the Nation's need to find a cure and a vaccine, including the Ryan White Comprehensive AIDS Resources Emergency Act (CARE) Act and the NIH Revitalization Act of 1993.

Currently, Federally sponsored activities include direct support for research, prevention and education, housing, medical care, support services, information dissemination, enforcement of civil rights, and assistance to international organizations and other nations. While Federal Agencies are responsible for responding directly to the epidemic of HIV and AIDS, they also collaborate with and provide support for State and local governments, academic institutions, private foundations, health care

institutions and community-based organizations, which often have substantial surveillance, prevention, and health care responsibilities.

## **PREVENTION**

The Nation's prevention goal is to develop effective prevention strategies that will reduce the number of new infections each and every year until there are no new infections. Achieving this goal will require a dedicated alliance between the Federal government, States, local governments, communities, businesses, non-governmental organizations, families, and individuals. Achieving this ambitious end will require a clear definition of the different roles and responsibilities of the Federal government, and an ongoing dialogue with its partners in the public and private sectors about the responsibilities each has in reaching this goal.

We know that HIV prevention works. We also know that the task of preventing HIV transmission faced by the United States in controlling the epidemic of HIV and AIDS has reached enormous proportions.<sup>12</sup> The Centers for Disease Control and Prevention (CDC) estimates that approximately 800,000 to 1 million Americans are presently HIV-infected, many of whom are unaware of their HIV status. Moreover, the CDC estimates that approximately 40,000 to 60,000 American will become infected each year. Many more Americans who are not presently infected are at risk for acquiring HIV. HIV infection is a unique prevention challenge because of the virus' virulence, the long period of time when people may not be aware they are infected, long duration of infectiousness, nearly always fatal prognosis, and potential for exponential spread. Moreover, HIV is transmitted

primarily as a result of personal and private individual behaviors -- sex and drug use. To be effective, HIV prevention programs must reach tens of millions of Americans who are characterized by a diversity of age, race, ethnicity, geographic locale, sexual orientation, and sexual and drug use behaviors.

Prevention activities are currently supported by several Federal Agencies. (See Appendix A.) Most Federal prevention efforts are funded by Department of Health and Human Services (HHS), although other Departments such as the Department of Defense (DOD), and the Department of Veterans Affairs (VA) also support prevention activities. These efforts reflect a continuum from surveillance to research to social marketing initiatives. Agency activities are also reflective of their respective missions. For example, the Centers for Disease Control and Prevention (CDC), the Agency with primary Federal HIV-prevention responsibilities, supports a wide range of surveillance and prevention projects, many in partnership with States, local governments, and community-based organizations. Other Agencies focus on specific aspects of prevention. For example, the National Institute on Drug Abuse (NIDA) and the Substance Abuse and Mental Health Services Administration (SAMSHA) support efforts to prevent HIV infection among drug users, while other Agencies support primary prevention efforts as part of medical care, such as at the veterans and military hospitals and clinics. The Health Resources and Services Administration (HRSA) also encourages

broader access to prevention information through the integration of prevention interventions into primary health care services and through support of early intervention services for low-income medically underserved persons. HRSA also has undertaken special initiatives designed to reduce perinatal transmission of HIV and has promoted primary prevention through the training of health professionals in the AIDS Education and Training Centers program.

The efforts of Federal Agencies as well as research conducted at universities and private organizations, have been instrumental in expanding our knowledge base about HIV prevention. However, significant gaps remain. We know from both formal research and community experience that developing prevention programs that are effective requires knowledge of who is becoming infected and of the behaviors that are enabling transmission, an understanding of the motivations for those behaviors, and an understanding of how best to reach people with messages that will ensure lasting behavior change.

Prevention priorities must be guided toward gaining knowledge that will improve our efforts to develop effective prevention programs. We need to improve our understanding of the major modes of transmission, close gaps in scientific knowledge, including identifying effective prevention models and strategies, and work towards eliminating gaps in program areas.

## **Opportunities for Progress**

### **Modes of Transmission**

An important part of strengthening prevention activities is to have a clearer understanding of who is being infected and what behaviors are placing people at risk for infection. Recent epidemiologic data show that the HIV epidemic continues to spread in the United States among people who engage in injection drug use and their sexual partners, young and minority men having sex with men, heterosexual transmission, and through perinatal transmission. Moreover, the youth of our country are becoming infected at an alarming rate -- 50 percent of new infections in the United States are in persons under 25 years of age. HIV is the leading cause of death in Americans aged 25 to 44 and it is likely that many of these people were infected while they were adolescents. Racial and ethnic minorities are also disproportionately represented among new HIV infections. As of October 1995, African-Americans accounted for 38 percent of newly reported AIDS cases and Hispanics represented 18 percent of new cases. These trends in the epidemic must be taken into consideration when prioritizing prevention research and service programs.

A crucial part of effective prevention strategies includes supporting adequate surveillance of HIV infection and related diseases in order to gauge future directions of the epidemic, and assess the effectiveness of prevention interventions. As previously

noted, the CDC is the Federal Agency with primary responsibility for monitoring the epidemic. Seroprevalence surveys provide information on the level of HIV infections in "sentinel" populations. The CDC AIDS case and case death reporting system provides useful data for assessing AIDS prevalence and mortality by gender, race/ethnicity, age, and mode of exposure. This surveillance system also provides essential data on HIV-related opportunistic infections.

There are, however, opportunities for refinement. Effective prevention intervention programs begin with sound information on who is at risk. Current CDC surveillance systems do not capture sufficient "front-end" information on the incidence and prevalence of HIV (not AIDS) in the population, and trends in modes of transmission and new infections. Collection of these data are needed as part of an enhanced effort to link surveillance and epidemiological data to priority setting, in addition to the design and evaluation of prevention programs. (These data must be collected with the appropriate confidentiality protections.)

The CDC has recognized the value of this approach and has incorporated data collection design into its community planning process. These shifts in data needs coupled with fiscal restrictions may also require that the CDC reevaluate and reconfigure its data collection efforts. As part of the Agency's implementation of the recommendations set forth in the external review of CDC's HIV prevention

strategies<sup>13</sup>, the CDC has initiated efforts to evaluate current data collection efforts and implement necessary changes, and this work should continue.

#### **Prevention Research<sup>14</sup>**

Factors that place individuals at risk for acquiring HIV infection are a complex combination of behavioral, social, cognitive, and biological influences. Given this complexity we must not *assume* we intuitively know which interventions will work, but instead base our efforts on sound research findings and evaluation. Experience has taught us that prevention efforts can be effective, but when they are it is because the intervention incorporates findings from both experience and relevant research. Behavioral research is a relatively young science and there are currently more questions than answers. The three main areas where gaps in knowledge have been identified are basic behavioral research, intervention research, and social marketing research.

**Basic Behavioral Research.** Information provided by the conduct of basic behavioral research should serve as the foundation for prevention programs. Basic behavioral research, similar to basic research in other areas of scientific inquiry, seeks to explain the determinants and causes underlying biological, behavioral, and social processes. HIV-related risk-taking behavior is often complex and influenced by a host of individual and environmental factors.

To capitalize on what is known and improve

HIV prevention programs that are targeted to reach a diversity of Americans, more information on the determinants of HIV-associated sexual and drug-using behaviors is needed. For example, although much has been learned about the basic biology of substance abuse, further elucidation of the mechanisms underlying addictive behavior may assist in the development of new therapeutic approaches to addiction, which may in turn reduce the number of new infections.<sup>15</sup> And although we have some information on relevant risk-taking behaviors, more information about knowledge, attitudes, decision-making processes, and beliefs about AIDS and other sexually transmitted diseases (STDs) is much needed. Such data enable scientists to establish theories of behavioral change, which then provide researchers with tools for identifying what approaches may be most effective for an individual or a community.<sup>16</sup> [Awaiting revised language from NIH.]

**Intervention Research.** A second major gap is research to improve prevention interventions, i.e., research that concentrates on modifying behaviors, such as those related to drug use and sexual practices. We know from other behavior-influenced diseases (such as hypertension) and practices (such as cigarette smoking and wearing seatbelts) that basic information about what motivates a person to exhibit these behaviors can be incorporated into intervention research to advance approaches to reducing unhealthy behaviors.

In HIV and AIDS, this intervention research

can focus on both individuals and communities, which often hold norms that influence personal behavior. Since the beginning of the epidemic we have made advances in our understanding of factors that are relevant to the design of intervention programs intended to reduce rates of HIV infection. This theoretically based intervention research has identified several significant predictors of changes in sexual and drug-using behaviors among gay men, adolescents, and heterosexual adults.<sup>17</sup> Studies have shown that community-based HIV risk reduction programs that are gender relevant and culturally sensitive can be effective.<sup>18</sup> A recent study has also provided a reason for optimism that the spread of HIV can be contained among injecting drug user populations when there is early community outreach and access to sterile injection equipment.<sup>19</sup>

However, despite this evidence of success, there is more that we need to know if we are to develop effective prevention programs for a diversity of Americans. We must incorporate findings from basic behavioral research into effective prevention interventions. One high priority area is research on interventions that lead to sustained behavior change and reduced recidivism. Another area for investment is research on cultural barriers and strategies to reach populations resistant to certain behavior interventions. A third area is research on the effectiveness of treatment for drug abuse, mental illness, and alcoholism in reducing HIV risk behavior.

Agencies supporting intervention and

behavioral research must include scientists from a broad range of disciplines in their planning activities and improve their data-sharing and collaborative efforts with Agencies responsible for implementing prevention programs. Enhancing the dialogue between researchers in these two related fields will invariably improve the development of effective prevention interventions.

**Social Marketing Research.** It is important that the findings from basic behavioral and intervention research be incorporated into prevention programs. Agencies supporting social marketing activities need to build on current knowledge in addition to strengthening efforts to understand barriers to the implementation and replication of promising prevention programs. Given the highly innovative nature of these endeavors, the CDC must consider providing broader technical assistance and training to community organizations. Moreover, a community-based effort that would test prevention models in a real-world setting should be carefully considered. [Awaiting additional language from NIH.]

We know from efforts in other countries that HIV-related social marketing efforts can be successful. However, we have not been as effective as we could be in disseminating information about effective strategies so that this knowledge can be employed in the design and implementation of prevention interventions. There *are* good models for prevention interventions that are not making their way to those on the front lines of the epidemic. Community-based organizations,

which are responsible for developing a large portion of the prevention programs often do not, or are not able to, take advantage of current knowledge about program effectiveness.

### **Prevention Programs**

In order to stop new infections, the results of basic behavioral, intervention and social marketing research must serve as the foundation for prevention intervention programs that reach people at risk for acquiring or transmitting HIV. Presently, the Federal government supports a range of programs that address the disparate needs of a number of at-risk populations. However, the shifting demographics of the epidemic coupled with restricted resources has resulted in gaps in program areas that limit the Nation's ability to prevent new infections. It is therefore important that prevention planners carefully prioritize their efforts based on local epidemiology.

**Community Involvement.** For prevention interventions to be effective they must reach communities at risk and be responsive to their unique needs. And for individuals to take control of their own lives in fighting the spread of this virus, they must first have the information and skills to protect themselves.

One of the most important innovations in the prevention area is community planning. The community planning process is an outstanding model of a Federal-local partnership. Through this effort, it is possible to establish joint goals for the

prevention of HIV that will meet Federal standards while remaining responsive to local needs. However, this process is early in its development and requires significant, ongoing leadership and technical assistance from the CDC if it is to fulfill its potential for good priority setting and decision making.

**Substance Abuse Prevention and Treatment.** Injection drug use is one of the major forces driving the epidemic with one third of all new cases are directly or indirectly related to this mode of transmission. Limiting the impact of substance abuse on the epidemic will require efforts on several fronts.

First, we need to improve the integration of HIV prevention activities and substance abuse treatment and prevention programs. The epidemics of substance abuse and HIV in this country are overlapping and highly interrelated, however, care and prevention services for HIV and substance are not. It is vital to continue efforts to integrate HIV prevention into current substance abuse programs and integrate substance abuse prevention into HIV prevention.

A second avenue for controlling the spread of HIV among addicted persons is enrollment into drug treatment programs. Substance abuse treatment is a form of HIV prevention. Moreover, substance abuse problems that contribute to the spread of HIV are not limited to injecting drug use. There is substantial evidence that use of alcohol and other substances can adversely influence risk-taking behavior. In addition,

it is estimated that ~~x~~ percent of the population is affected by alcohol abuse and other non-injectable drugs.

Fundamental to the success of an integrated approach would be the continued expansion of educational activities to prevent substance abuse, and increased outreach efforts to encourage active substance users to seek treatment. We also need to ensure that drug treatment services are available in sufficient numbers for a range of addictions for those in need of such services. This would include services that accept pregnant women or women with children, indigent members of the community and adolescents.

Work on this issue has begun and will continue. The CDC has an initiated State-by-State discussion, including meetings with State Legislators, regarding HIV prevention issues. The CDC is also working with the National Conference of State Legislatures to provide a forum for a broad spectrum of views on this important issues.

**Treatment for Sexually Transmitted Diseases and Tuberculosis.** Studies have shown that the presence of sexually transmitted diseases (STDs) can significantly increase the efficiency of HIV transmission, even by as much as 20 times. Studies have also shown that widespread treatment of STDs in certain communities has led to a 40 percent reduction in new HIV infections in these groups.<sup>20, 21</sup> These data suggest treating STDs can be an effective HIV prevention strategy and points to a need for all clinicians to be vigilant in efforts to prevent and treat STDs.

Persons who are HIV positive are at significant risk for developing of *M. tuberculosis* (TB) disease. Studies suggest that the risk of developing TB disease is 7 to 10 percent each year for persons who are infected with both TB and HIV, whereas the risk is 10 percent over a lifetime for persons not infected with HIV.<sup>22</sup> In addition to the health implications for infected persons, there is an increased risk of transmission of TB to household members, health care workers, and other persons having regular contact with the person with TB.

It is important that Federal and State efforts to reduce the incidence of sexually transmitted diseases (STDs) include an HIV prevention element, and, that HIV prevention programs incorporate STD prevention and treatment efforts. Moreover, the traditional model of targeting most STD prevention efforts towards individuals who have already contracted one STD is not necessarily effective for HIV prevention. Enhanced and innovative linkages between STD and HIV prevention need to be established. The newly organized National Center for HIV/STD/TB Prevention at CDC reflects the importance of integrating these inter-dependent aspects of the epidemic and illustrates our determination to integrate and coordinate HIV, STD, and TB programs.

**Integration Into Primary Care.** To reach our prevention goal, we must also improve the integration of prevention activities and messages into primary health care services. HIV counseling and voluntary testing often provide an important bridge between HIV prevention and care for many at risk

persons, including youth, women, and ethnic minorities. To assure that all persons seeking HIV testing can have access to such services, the CDC's counseling and testing guidelines should acknowledge and address the needs of persons seeking such services, and provide training for personnel at CDC-funded sites.

Incorporating a patient's sexual and drug using history when a medical history is taken, offering HIV-related counseling and voluntary testing, and working with HIV positive individuals so they do not infect others is also important. It also means offering pregnant women information about and access to AZT during pregnancy to reduce the risk of perinatal transmission. Training should be made available to improve primary care providers' skill, comfort level and sensitivity in these areas.

Achieving this level of integration will require active collaborative efforts on the part of individual physicians, nurses, other clinicians, managed care plans, medical schools, and professional organizations in addition to State, local, and Federal governments.

**Evaluation.** It is important to assess the effectiveness of the prevention interventions that have or will be implemented. Prospectively set performance measures can be used as a basis for evaluation and program improvement. Incorporating effectiveness measures must become a routine part of all Federally-funded programs. It is only through sound evaluations that we will be able to determine

***The National Strategy for HIV and AIDS***  
***Draft for Office of National Drug Control Policy Review: 6.11.96***

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whether our efforts have been effective in slowing the epidemic. Achieving this will also require careful examination of what programs should be continued, what activities need to be initiated, and a awareness that a reconfiguration of some program priorities may be required.

## **RESEARCH**

One of the Federal government's goals is to provide strong support for research in order to find treatments and a cure for those currently infected, and a preventive vaccine to protect the uninfected. It is research that will enable us to reach these goals and until they are a reality, the Federal government must provide solid ongoing support for basic and clinical research.

Achieving this goal will require committed collaborative efforts among the Federal government, universities, researchers, the advocacy community, persons living with HIV and those at risk for infection, communities where research is conducted, charitable organizations, pharmaceutical companies, biotechnology firms, and other parts of the private sector. It will also require an ongoing dialogue between the public and private sectors.

At present, a number of Federal Agencies play a significant role in U.S. AIDS research efforts. (See Appendix B.) These endeavors range from basic molecular research to clinical research to health services research. The National Institutes of Health (NIH) supports a significant portion of these efforts. NIH funds research on HIV-related natural history and epidemiology, etiology and pathogenesis, therapeutics, vaccines, and behavior. As part of its mission to protect and maintain a viable fighting force, the Department of Defense supports clinical vaccine and therapeutic research. The Agency for Health Care Policy and Research (AHCPR)

funds health services research to help determine which medical approaches are the most cost effective. The Department of Energy (DOE), through its support of technologically advanced equipment, provides the opportunity for Federal and private researchers to share resources and thereby analyze molecular structures that, without such equipment would not be possible. The Centers for Disease Control and Prevention (CDC) monitors and assesses modes of and risk factors for transmission through epidemiologic and laboratory studies. The Agency also supports facilities employing sophisticated methods for identifying viral variants.

### **Contributions of Research**

[Awaiting revised language from NIH.] The Nation has already reaped some of the benefits of supporting research in general, and HIV-related research specifically. AIDS research has provided advances for treatment of other diseases. For example, HIV-related research has contributed to progress in treating breast cancer. Research revealed that by blocking cytokine receptors, tumor cell growth could be inhibited; this finding led to the development of new treatments for breast cancer.

Advances in treating conditions resulting from immunosuppression have come from HIV-targeted research. One of the most promising experimental therapies for advanced breast cancer is high-dose chemotherapy followed by bone marrow transplantation, but the treatment causes

profound immunosuppression; AIDS-related research has provided valuable insights regarding the management of these patients.

HIV-related research has also accelerated study of the human immune system which has in turn improved our ability to understand and treat other conditions such as cancer and autoimmune diseases, including systemic lupus erythematosus, type I diabetes mellitus, rheumatoid arthritis, and multiple sclerosis.

Research involving the blood/brain barrier has led to a better understanding of the mechanisms by which infectious agents spread into the nervous system. These findings provide valuable clues for research on Alzheimer's disease, dementia, multiple sclerosis, neuropsychological disorders, encephalitis, and meningitis. Moreover, prior to the AIDS epidemic, little investment was made in research to treat viral diseases. Studies to develop anti-HIV therapies have improved our understanding of more viral diseases and led to development of treatments for many other diseases.

Research investments made before the advent of the AIDS epidemic produced a body of scientific knowledge that enabled researchers to more quickly pursue theories and avenues of investigation. For example, research previously conducted on the immune system in general, and CD4+ cells in particular, provided early insights into the pathogenesis of HIV. Research investments in retroviruses yielded invaluable information for identifying HIV as the etiologic agent of the emerging epidemic,

and advances in molecular biology provided researchers with the tools to understand HIV's structure and develop drugs based on that information.

Due in great part to Federally-sponsored research, persons with AIDS now live twice as long as they did a decade ago. Clinicians now have a growing array of medication to treat and in some cases prevent a variety of HIV-associated opportunistic infections. An NIH-sponsored study found that it is possible to dramatically reduce the chance of transmission of HIV from mother to infant. Data from federally-sponsored prospective epidemiological studies are helping scientists understand the factors that enable long-term non-progressors to live many years after infection without presenting clinical signs of progression to AIDS. [Awaiting revised language from NIH.] Understanding what happens in these non-progressors may help researchers develop better therapies and a vaccine.

And there is further reason for hope. Scientists now believe that a vaccine is possible. New classes of anti-retroviral therapies appear to be powerful in controlling the virus. Combination therapies are offer great potential promise in this area and in preventing perinatal transmission. In addition, the Food and Drug Administration, through its accelerated approval program, is now approving drugs faster than ever before and faster than any European nation.

However, despite these advances, many complex biomedical and behavioral challenges remain. Identifying the most

promising scientific avenues, and having the appropriate structures and processes in place to ensure that the Nation capitalizes on these opportunities, will require a considered and coordinated effort.

### **Opportunities for Progress**

**Coordinating Federal Research.** Developing and implementing the Federal government's AIDS research agenda presents both scientific and logistical challenges. Planning and overseeing this massive Federal effort requires coordination efforts at two levels -- one within NIH and the second among the Departments and Agencies supporting HIV research.

Within the NIH, the Agency with the largest portfolio, research is supported throughout 24 institutes, centers, and divisions (ICDs). In order to better plan, coordinate, and fund the AIDS research activities of these ICDs the Congress, through the NIH Revitalization Act Amendments of 1993, provided the Office of AIDS Research (OAR) with new oversight and budget authorities. As part of fulfilling the requirements of the law, the OAR develops a yearly NIH plan and budget for AIDS research and receives directly from the President and the Office of Management and Budget (OMB) a consolidated appropriation for AIDS activities at NIH. This single appropriation allows the OAR to effectively prioritize research resources on the basis of sound scientific judgment and provides flexibility for pursuing the most promising research opportunities.

It is crucial that the authority granted OAR in the revitalization legislation, including the consolidated appropriation, be supported and maintained. With such a large research enterprise it is essential that there is oversight and accountability so the most promising approaches are vigorously pursued, gaps in research areas are identified, and the individual Institutes have both the scientific and administrative assistance they need to effectively collaborate with other NIH institutes.

It is also clear that while NIH supports a significant portion of HIV-related research, other Agencies and Departments support a broad spectrum of research related to HIV and AIDS. Multiple Federal Departments and Agencies have responded with research initiatives that bring to bear their unique capabilities and strengths. For the government to effectively support a diversity of promising approaches, these research efforts must also be well-planned and coordinated. To achieve this the Director of the Office of National AIDS Policy coordinated an inter-departmental working group, chaired by the Director of the Office of AIDS Research, whose charge it was to develop a coordinated plan and budget specifically for HIV and AIDS research across all Agencies Departments. [Awaiting additional language from NIH.]

The first Federal Biomedical and Behavioral Research Plan and Budget for HIV and AIDS was completed in April 1996. The development of this plan brought together representatives from the National Institutes of Health, the Centers for Disease Control

*The National Strategy for HIV and AIDS*  
*Draft for Office of National Drug Control Policy Review: 6.11.96*

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and Prevention, the Food and Drug Administration, the Department of Defense, the Department of Energy, and the Department of Veterans Affairs. This plan provides an initial blueprint to focus and coordinate existing Federal HIV/AIDS research initiatives and thereby utilize available resources more efficiently and effectively. It also serves as a foundation for continued planning and evaluation.

**Vaccine Development.** Several major challenges currently face the U.S. and the world in the HIV vaccine development effort. The first is to surmount the daunting scientific and social challenges, and the second is to ensure the development and testing of promising vaccine candidates.

On the scientific level, researchers presently hold two major views regarding the most promising approaches to vaccine development. Some scientists maintain that there is not sufficient information about the virus to warrant efficacy trials and there is a need to gather more basic science information to guide us. Others assert that only clinical efficacy trials in humans will provide the answers that will lead to the development of a successful candidate. This group believes that if a safe candidate is available, it is not necessary to resolve all of the scientific questions before proceeding, and, that in the face of a global emergency testing in people should begin immediately. Both groups have valid arguments.

The issues driving this debate are scientific and social, and stem from the contrasting ways different parts of the world are

experiencing the epidemic. Some regions of the world have already experienced the devastating consequences of the epidemic while, in other areas, the epidemic is in its early stages. Some governments have shown a greater interest than others in preparing for vaccine trials as a method of slowing the growth of the epidemic in their countries. [Awaiting revised language from NIH.] Both the social and scientific issues must be considered when planning trials. Given the State of scientific knowledge, there is some consensus that both the basic and empirical avenues can and should be pursued.

Both approaches face significant obstacles and it is clear that the developing a vaccine cannot be accomplished by the government or the private sector working apart -- a public-private partnership will be needed. In order to identify areas for fruitful collaboration and to accelerate the pace of development for vaccines, the Vice President convened a meeting of government scientists and leaders of the pharmaceutical and biotechnology industries to identify barriers to the development of these agents. Further dialogue involving key players regarding critical problems, and opportunities for development, and viable solutions has begun and will continue. [Awaiting revised language from NIH.]

In addition to effective collaboration with private sector partners, it is also vital that the Federal effort be well-coordinated. The Federal linkages that were strengthened during the development of the Federal Biomedical and Behavioral Research Plan

and Budget for HIV and AIDS should be utilized in furthering coordination. [Awaiting additional language from NIH.]

**Microbicides.** Many scientists believe that the prevention of sexually transmitted HIV infection will depend on the development of a safe, effective, female-controlled mechanical and chemical barrier methods that will block HIV transmission or prevent other sexually transmitted infections. [Awaiting revised language from NIH.] Worldwide over 80 percent of HIV infections are acquired heterosexually and women are more easily infected than men. In the U.S., the infection rate among women is rising dramatically. Moreover, the risk of becoming infected or infecting others is substantially increased by the presence of other STDs<sup>23</sup>. Microbicides could provide an easily available and inexpensive protection option for millions of women worldwide.

The barrier methods that are currently available have limitations. Most require consent, if not active participation of the male partner, and therefore cannot be independently used at the discretion of the female partner. Although epidemiological studies have demonstrated that the correct and consistent use of condoms will reduce the risk of acquiring HIV and other STDs there are many situations in which interpersonal, social, or cultural barriers interfere with a woman's ability to successfully negotiate condom use. The need for a method that can be employed by women is based on the prevalence of non-consensual sex, sex without condom use,

and risky behaviors that occur without partner knowledge. [Awaiting revised language from NIH.]

The development of this important prevention option will depend on strong support for basic and clinical research. Microbicides are a promising approach, but will require preliminary Federal support before they reach a stage where the pharmaceutical or biotechnology industries can assume a lead role. Discussions among Federal Agencies, the private sector, and advocacy groups have been ongoing and should continue in order to identify areas for worthwhile collaboration and hasten the pace of development. [Awaiting revised language from NIH.]

**Examining the Impact of HIV on Youth.** HIV-related research has made great strides on many fronts, however, adolescents have not received the full benefit of research discoveries. To date, HIV research efforts have primarily focused two specific populations: infants and adults.

But scientific information exists to indicate that HIV may behave differently in infected adolescents and that there are adolescent-specific health-care needs that must be addressed. Adolescent treatment approaches may vary from those used for adult or infants. Because little definitive research has been conducted to date with HIV-positive adolescents, the specific impact of puberty on the course of HIV infection has not yet been determined. Behavioral trends that play a key factor in treatment and prevention have also not been sufficiently

studied.

Adolescents must become a bigger part of the research process. The NIH and the Food and Drug Administration should examine options for lowering barriers to participation and continue to encourage sponsors to enroll adolescents, when feasible and appropriate, in HIV/AIDS clinical trials.

There is also need for adolescent-relevant information on the part of clinicians and researchers. The Public Health Service should continue to develop in collaboration with researchers, clinicians, and the infected and affected community, clinical practice guidelines and expeditiously disseminate the latest information on state-of-the-art therapies, options for trials and eligibility criteria for entry into them, and health care and prevention techniques to U.S. and international communities affected by HIV/AIDS.

**Clinical Effectiveness Research.** Due in part to the FDA's accelerated approval program<sup>24</sup>, the Federal government is now approving new treatments in record numbers and at record speed, but it is not always known whether a treatment confers a clinical benefit for the person. Specifically, while some treatments have shown promise based on surrogate markers and/or laboratory tests, data regarding clinical effectiveness are increasingly unavailable. For example, we do not know the optimal stage in the course of HIV disease to begin treatment, for which patient groups, with which regimen, or with single or combination therapy. We also do not know when it is

appropriate to switch or add therapies.

If these studies are not done there will be little data describing which of the available treatments is more effective and for whom, and under what circumstances. As a result, patients may be receiving less effective treatments or combinations of treatments, and Federal programs such as Medicaid and Medicare and private insurers may be paying for treatment strategies that are not optimally effective.

With the advent of accelerated approval by the FDA it is incumbent on the government to ensure that post-marketing effectiveness studies, currently mandated through regulation are carried out. In order for the results to be relevant to as many persons as possible, it will be necessary that these studies include people representing a diversity of race, ethnicity, gender, age, and drug using behaviors. To develop a mechanism for conducting such studies, the Vice President has initiated discussions to examine possible options. Participants include pharmaceutical firms, public and private payors and insurers, researchers, the FDA, the NIH, and the advocacy community.

**Public-Private Partnerships.** As has been noted previously, a key role for the Federal government is to act in partnership with the private sector and support areas where there is a market failure, i.e., areas where industry is unlikely to pursue research that would be beneficial to the public health. Vaccine development is one such area, but there are others. The Department of

*The National Strategy for HIV and AIDS*  
*Draft for Office of National Drug Control Policy Review: 6.11.96*

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Defense has been successful in developing partnerships in the conduct of vaccine trials and this effort should be strengthened. As noted previously, microbicides (i.e., chemical barrier methods for preventing HIV transmission) are a promising approach, but will require preliminary Federal support before they reach a stage where the private sector can assume a lead role. [Awaiting additional language from NIH.]

It is also unlikely that the free market system will push the implementation of head-to-head clinical trials of therapies that have been approved or are in development. However, information about these therapies is important to improving patient care and ensuring that the Nation's health dollars are wisely spent. The National Institutes of Health and Veteran's Administration have been successful in carrying out this type of valuable research in collaboration with the pharmaceutical industry and these efforts should continue. It is unlikely that the private sector would support research for therapies that are on the market but have not been tested in controlled clinical trials, such as alternative therapies. However, through collaborative partnerships including the NIH, studies of alternative therapies have been conducted; these are important efforts that should continue. [Awaiting additional language from NIH.]

It is also cost effective for the government to provide access to sophisticated equipment and personnel that can be shared among many researchers in both the private and public sectors. For example, the

Department of Energy has supported sophisticated imaging equipment that would be prohibitively expensive for individual researchers or companies to purchase. This shared resource that has accelerated our understanding of molecular structures in a number of research fields, including HIV research. Information gained from this research can form the basis for targeted drug design and development. [Awaiting additional language from NIH.]

**Research: An Investment for the Future.** And finally, research is an investment in our future. It must receive consistent and adequate funding if we hope to bring the best and the brightest to meet the research challenges that will lead to a cure, better therapies, and a vaccine.

At present, the NIH receives many more outstanding research applications than it is able to fund; these unfunded proposals represent a lost opportunity for scientific progress. Other Departments and Agencies, such as the Department of Defense and Veteran's Administration also support crucially important research that strengthens the overall U.S. research effort. Research has been key to improving lives and the Nation must continue this investment. [Awaiting additional language from NIH.]

## **CARE & SERVICES**

One of the national goals is to ensure appropriate care for all persons living with HIV and AIDS. Achieving the goal of ensuring appropriate care of all Americans, including those living with HIV, will require a dedicated alliance among the Federal government, States, the private sector, local communities, community-based organizations, clinics, families, and individuals.

### **Background**

Persons living with HIV finance needed health care services through a variety of mechanisms. Currently, nearly 50 percent of adult Americans and 90 percent of children living with AIDS receive their medical coverage through the Medicaid program and another 5 percent receive Medicare benefits. An estimated 15 percent of people living with AIDS have private health insurance and the remaining 30 percent are uninsured and must rely on personal payment or charity care. For the remainder, their lives often depend on the Federal health care safety net.

For those who qualify, care and services are provided through a number of Federal Agencies (See Appendix C), many in cooperation with local organizations and the AIDS community that have admirably served those living with HIV. Taken together, these efforts form a valuable if incomplete safety net for some of the most vulnerable people in our Nation.

After Medicaid, the centerpiece of this safety net is programs funded through the Ryan White Comprehensive AIDS Resources Emergency (CARE) Act of 1990, administered by the Health Resources and Services Administration (HRSA). It was established to fill gaps in coverage and build systems of care to create access to health care for people living with HIV/AIDS. Titles I and II of the CARE Act provide funds for outpatient care, support services, and case management that are given to cities and States primarily on a formula basis so the areas most affected by the epidemic receive a proportional share of available dollars. Title II also provides drug reimbursement funding for persons living with AIDS. Title IIIb of the Act provides early intervention services such as counseling and testing, medical care, and educational services for medically underserved persons with the goal reducing HIV-related illness. Title IV seeks to increase the availability of care and services for women, infants, children, and youth in a community-based family-centered system of care. HRSA also provides primary care to persons living with HIV through its Community Health Centers and Maternal and Child Health Programs.

Other sources of primary care supported by the Federal government include the Department of Defense, the Department of Veterans Affairs, and the Indian Health Service/DHHS which provides health care for HIV-infected Native Americans and Alaska Natives. Additionally, the Bureau of Prisons within the Department of Justice provides care for HIV positive persons in

Federal prisons.

Housing assistance is provided by the Department of Housing and Urban Development (HUD) through their Housing Opportunities for Persons with AIDS (HOPWA) and other programs. These programs work in partnership with local initiatives incorporating housing assistance into a community's continuum of services.

### **Opportunities for Progress**

The challenge before us today, especially in light of the restricted fiscal environment, is to ensure that persons living with HIV receive the care they need so they may have the opportunity to live productive lives. To achieve this, AIDS care and service programs must build upon past successes, continue to improve prioritization efforts, improve accountability, and increase the cost-effectiveness of services they provide.

**The Health Care Safety Net.** The cornerstone of care for people living with AIDS in the U.S. is Medicaid. Nearly 50 percent of all Americans living with AIDS -- including 92 percent of children with AIDS -- rely on Medicaid for their sole source of health coverage. Medicaid provides coverage for hospitalizations, physician visits, x-rays and laboratory tests, home health care, nursing home care, and outpatient prescription drugs. These services extend the length and the quality of life for people living with HIV and AIDS. In fiscal year 1996, Federal Medicaid spending for people living with AIDS is

estimated at \$1.8 billion, nearly six times the amount expended on the Ryan White CARE Act.

Maintenance of the Federal guarantee of Medicaid coverage for eligible individuals is essential to the continued ability of the Nation to respond to the health care needs of people living with HIV/AIDS. Of particular importance is the maintenance of a Federal definition of disability. The 30-year State partnership in Medicaid also must be maintained while the program is made more flexible for State innovations.

With a strong Medicaid program in place, it continues to be vital that the Ryan White CARE Act be maintained and expanded to fill the gaps in coverage. Many people with HIV and AIDS are too poor or too disabled to work yet they are not poor enough or disabled enough to qualify for Medicaid. For them, and for their families, the CARE Act provides essential protection.

**Integrated Continuum of Care.** Many health care providers believe that one of the most potentially effective approaches to treating HIV positive persons, in addition to reducing the spread of infection, lies in providing people access to an integrated continuum of health care services. This includes counseling and testing, comprehensive health care, home health care, and access to substance abuse treatment and prevention services.

One of the most powerful methods of recruiting people into primary care is knowledge of serostatus -- persons who

know they are HIV positive are more likely to seek health care. Counseling and testing services can serve as a gateway to this care. Unfortunately, the majority of Americans who may be at risk for HIV infection do not know whether or not they are HIV positive. There is a need to develop better outreach education in order to encourage people to come in for counseling and testing and link them to appropriate services as needed. Without the linkage of testing to medical care, the opportunity to prolong life is lost.

Linking an HIV-positive person with care also provides an opportunity for education about behaviors which may reduce their chances of infecting others. For example, this can mean offering addiction treatment or offering pregnant women information about and access to AZT during pregnancy to reduce the risk of perinatal transmission.

As noted in the Prevention Section, achieving this level of integration will require active collaborative efforts on the part of individual physicians, nurses, other clinicians, managed care plans, medical schools, and professional organizations in addition to State, local and Federal governments.

**Housing Services.** Housing is an important element in the effort to provide comprehensive care for persons living with HIV. It is the foundation upon which any program of care or services must be built. Without stable housing, a person with HIV/AIDS has diminished access to programs and services and a diminished opportunity to live a productive life. It is

estimated that up to 50 percent of persons living with HIV and AIDS will become homeless or are at risk for becoming homeless during the course of their illness.<sup>25</sup>

Persons living with HIV face significant obstacles locating affordable housing. The private market alone does not consistently meet the basic housing needs of persons living with HIV and their families, as housing must often be provided in connection with specialized services that enhance an individual's or family's ability to live independently. In addition, persons living with HIV must also overcome reduced housing options due to unfounded fears and prejudice regarding AIDS.

Housing assistance is an area that requires significant community involvement and support if it is to be successful. Many communities are part of new efforts to comprehensively plan for the housing needs of their residents, including assessing and addressing the needs of residents living with HIV/AIDS.

The HOPWA program was created in 1992 to provide communities with a tool to meet the increased need for resources, effective planning, and coordination with existing public and private efforts. The program is representative of HUD's "Continuum of Care" approach to building local systems to address homelessness. Moreover, it is estimated that the cost of providing housing services in a HOPWA-funded residential facility is far less than the average day in the hospital.

To further foster community involvement, HUD has also established the Consolidated Planning process for communities that receive funds under the Department's economic and community development programs, including recipients of HOPWA formula allocations. In addition, the Community Development Block Grant (CDBG) and the HOME affordable housing program as well as Public Housing programs are key resources that are available to communities, contingent on eligibility, space availability and local priorities.

Providing consistent funding for the housing component of the safety net with programs such as community-oriented programs HOPWA must be a Federal priority. Moreover, integrating housing services into other programs and ensuring a shared responsibility between Federal, State, local governments and community organizations is another important step in assisting communities to build seamless systems of support for our most vulnerable citizens. Efforts are underway to improve inter-departmental coordination and should continue.

**Prisoners.** There are also groups of people, such as prisoners, who are not served by these traditional safety net programs. Most prisoners living with HIV are incarcerated in State and local prisons. Medical care for Federal prisoners is provided under the direction of the Department of Justice's Bureau of Prisons. Identifying the HIV positive prisoners and ensuring them access to quality care for incarcerated persons is

especially challenging. Prisoners do not have the choice of seeking care outside the prison setting and are dependent upon the prison staff to ensure that appropriate care is provided. They also may have difficulties regarding confidentiality, trust, and less access to research opportunities.

Improving access to appropriate HIV-related care in prisons must be a priority. At the Federal level significant advances are being made in the quality of care, improved coordination, and developing models of care. Improving the quality of care at non-federal prisons will require improving the knowledge and skill of the health care teams in the prisons, strengthening linkages between prisons and outside public health Departments and Agencies, and improving discharge planning. These efforts can serve to improve discharge planning for HIV positive prisoners at the time of their release from prison.

**Program Coordination.** For care and services to have the most beneficial impact they should be offered as part of a continuum of care. For organizations on the front lines of the epidemic, building a comprehensive integrated program requires applying to numerous Federal Agencies. For example, Creating a community program that integrates primary care with substance abuse treatment and prevention, and sexually transmitted disease screening, prevention, access to clinical trials, and housing assistance would require separate applications to SAMSHA, HRSA, CDC, NIH, and HUD.

Efforts to simplify federal funding applications to facilitate improved integration of service programs have already begun. For example, HRSA and SAMSHA have issued joint announcements and the HUD and HRSA have issued a joint announcement for the Special Projects of National Significance (SPNS) program. These efforts to improve integration should be continued and expanded.

**Evaluation.** Strong Federal support for these safety net programs must go hand-in-hand with improved accountability and priority setting. Evaluating current activities can provide valuable information for planners and those on the frontlines of the epidemic. It can assist us in providing better care to persons living with HIV. In an era of limited resources coupled with a demand for cost effective services of high quality, we must use all the tools available to us if we are to help those persons living with HIV.

**Quality of Care.** Federally supported programs can and should consistently provide quality care. Through the efforts of researchers and clinicians, it has been proven that quality care for HIV positive persons is possible, but quality care is not consistently available throughout the health care system. Establishing a standard-of-care and ensuring consistency in care delivery will require increased training for health care professionals and more accountability through the use of performance measures for quality care.

A Federal program that has achieved success

in improving the knowledge and skills of clinicians is the AIDS Education and Training Centers (AETCs) effort sponsored by the Health Resources and Services Administration. A major goal of the AETC program is to train health care professionals in the prevention, early diagnosis, and treatment of HIV infection.

However, this program alone cannot ensure that all health care providers have the knowledge and skills required to provide satisfactory care for HIV positive persons. Achieving this goal will require the cooperation of Federal Agencies, States, professional organizations, professional and medical schools, and individual clinicians.

## **INTERNATIONAL ACTIVITIES**

AIDS is a global pandemic. In the United States it is estimated that between 800,000 and 1 million people are currently infected with HIV. The World Health Organization (WHO) estimates that 18.5 million adults and over 1.5 million children are currently infected worldwide and there will be 10 to 15 million orphans worldwide attributable to HIV/AIDS by the year 2000. WHO also estimates that two to three million new HIV infections can be expected annually, and by the year 2000, thirty to forty million people will have been infected around the globe.

The pandemic jeopardizes decades of economic and social advances in many developing nations. In Africa and Asia, economic advances are threatened, and in some cases, may be reversed due to the pandemic of HIV and AIDS. Socio-economic studies have shown a decrease in overall domestic savings and investment levels, negative effects on foreign investments, reductions in the volumes of imports and exports, and a reduction in receipts from tourism.<sup>26</sup> In many countries, governments will be forced to cope with increasing numbers of cases, weakened health care systems, a deleterious economic impact on the most productive segments of society, and the reduction in the number of healthy men and women able to serve in the government and the military.

At present several Federal Agencies are working at slowing the AIDS epidemic internationally. (See Appendix D.) The Department of State has worked with other

Departments, Agencies, and non-governmental organizations to develop a framework to guide U.S. foreign policy in the global efforts against HIV and AIDS. The major areas identified for U.S. leadership are: preventing new infections; reducing the personal and social impact of the pandemic; and mobilizing and unify national and international efforts. The U.S. Agency for International Development (USAID) also has a leadership role in the global HIV effort through development assistance, research and policy formation. USAID focuses its strategy on developing prevention programs based on proven interventions, addressing social, cultural, regulatory and economic issues related to HIV/AIDS and other sexually transmitted infections, and developing and testing new interventions and methods to prevent transmission and mitigate the impact of the epidemic. The U.S. Information Agency (USIA) supports programs that promote dissemination of U.S. policies and information related to HIV and AIDS; and the Peace Corps trains a portion of its volunteers to directly address HIV-related concerns in their countries of placement. In addition, several Agencies support research overseas, including the National Institutes of Health, the Centers for Disease Control and Prevention, and the Department of Defense (DOD). The DOD is conducting clinical trials of candidate HIV vaccines in Thailand and NIH (working in collaboration with USAID), supports basic scientific studies on social and behavioral aspects of AIDS in developing countries. [Awaiting additional language from NIH.] The results of the studies ultimately will be used to develop

interventions to reduce behaviors that place individuals at risk for contracting HIV infection.

### **Opportunities for Progress**

**International Leadership.** The United States has established a global leadership role in combatting the epidemic. This leadership must continue. The U.S. strongly supports the newly established Joint and Co-sponsored United Nations Programme on AIDS (UNAIDS).<sup>27</sup> Moreover, the U.S. is a member of the governing body of UNAIDS.

The U.S. also supports efforts to more effectively make use of available resources as well as to encourage non-traditional donor countries to provide much needed contributions. Supporting UNAIDS and its innovative programmatic efforts, and its goal of working to increase the availability of therapeutics (and vaccines when developed) to the residents of developing countries is not only morally correct, but also furthers U.S. interests by promoting economic and social stability worldwide.

**Sharing Technology and Bringing Lessons Home.** In addition to financing the development of large scale, comprehensive AIDS prevention programs in many countries, USAID has gained valuable insights and lessons from experiences from these countries and is applying them to U.S. populations.

Based on the Vice President's "Lessons without Borders Project" initiative to bring

lessons learned abroad home to inner city and rural areas with problems similar to those experienced overseas, this initiative creates linkages between U.S. community organizations and international projects. The U.S., through its various Agencies will continue to build and strengthen networks that will facilitate leadership, coordination and transnational approaches to AIDS prevention and control programs and AIDS related research; exchange culturally and linguistically appropriate educational and training materials; and demonstrate the bidirectionality of USAID international programs and its potential impact on US based programs, and U.S. based non-governmental organizations.

**Program Coordination.** One of the most challenging aspects of the U.S. effort is effective coordination among a host of Agencies with varied missions and activities. The State Department and Agencies such as USAID and USIA are primarily focused on country-specific activities, that include many HIV-related objectives. Other Agencies, such as NIH and CDC, also support international activities. [Awaiting additional language from NIH.]

These differences in focus present challenges in effectively planning, coordinating, and evaluating the overall U.S. international effort. Therefore, in order to improve this endeavor, the Agencies supporting international activities must develop a mechanism for identifying and coordinating this effort.

## **TRANSLATION OF RESEARCH INTO PRACTICE**

An important element in our fight against AIDS is ensuring that hard won research advances are translated into practice (i.e., ensuring that new knowledge is incorporated into the standard practice of clinicians, service providers, and health educators caring for persons living with HIV). The increasing presence of HIV in every community necessitates that all health care providers become knowledgeable about assessing risk, promoting prevention, and caring for persons with HIV.

Improving the translation of research advances into daily clinical practice will require an ongoing collaborative effort on the part of the Federal government, individual health care providers, medical schools, professional organizations, international organizations, health centers and hospitals, and other parts of the private sector.

Information dissemination activities fall under the missions of several Agencies. (See Appendix E.) The National Institutes of Health (NIH) supports a broad range of efforts including a "Clinical Alerts" mechanism for the dissemination of clinical trials results to health professionals, the media, and the general public. DHHS supports and directs the International HIV/AIDS Clinical Conference Call series which disseminates critical, state-of-the-art clinical care information to primary care providers via live worldwide audio teleconferencing. NIH also supports publicly

available computerized databases such as AIDSDRUGS, AIDSTRIALS, and AIDSLINE. In addition the toll-free 1-800 TRIALS-A AIDS Clinical Trials Information Service (ACTIS) is co-sponsored by NIH, CDC, and FDA. [Awaiting additional language from NIH.] The Centers for Disease Control and Prevention (CDC) disseminates information through hotlines such as its toll-free 1-800-HIV-0440 HIV/AIDS Treatment Information Service (ATIS) and the AIDS Information Clearinghouse.

The CDC also issues guidelines for health professionals through its *Morbidity and Mortality Weekly Report*; such guidelines have included The U.S. Public Health Service Recommendations for HIV Counseling and Voluntary Testing for Pregnant Women. The Agency for Health Care Policy and Research (AHCPR) has published a series of HIV-related clinical practice guidelines for clinicians and companion pamphlets for their patients; an example of these materials is clinician guidelines for the evaluation and management of early HIV infection. The Health Resources and Services Administration has also developed guidances for its CARE Act grantees, funds an AIDS warmline that responds to questions from clinicians across the country, and directs a nationwide system of AIDS Education and Training Centers that provide state of the art HIV clinical information to health care providers.

## **Opportunities for Progress**

Due in part to Federally-sponsored information dissemination activities, dramatic changes in the way HIV is treated have taken place over the last 15 years. However, despite these successes, there are still areas for improvement. For example, an AHCPR-supported study indicated that primary care physicians may miss significant HIV-related symptoms during patient examinations.<sup>28</sup> Other research indicates that a disturbing number of clinicians do not use universal precautions in the course of routine patient care.<sup>29</sup>

We are also at a stage, unlike in the beginning of the epidemic, where research advances are coming more frequently. In the case of the NIH study that demonstrated it is possible to block perinatal transmission by administering a specific AZT regimen to the mother and baby, it became clear that this scientific breakthrough required a change in the standard of care and action by a number of Federal Agencies. This change also required the development of new testing and counseling guidelines to reflect the new options available to women. And it meant that for patients enrolled in Medicaid and Medicare to receive access to this breakthrough, a policy change on the part of the Health Care Financing Administration (HCFA) was required.

**State of the Art Guidelines.** One of the most difficult tasks for clinicians and patients is interpreting the patchwork of data and articles regarding treatments and converting it into a therapeutic strategy. With every research breakthrough, this task becomes more difficult. It is essential that

practical information for practicing clinicians and their patients be provided in a timely manner.

The Federal government must develop a mechanism for ensuring periodic assessment of the state of the art, ensuring that essential information can be found easily, and disseminating that information widely. This will require collaboration with industry, government, and professional groups.

**Coordination of Federal Activities.** Enhancing coordination of information dissemination activities among Public Health Service Agencies is an important priority. Within the DHHS, the Office of HIV/AIDS Policy has the lead responsibility for coordinating the HIV-related activities of the Public Health Service Agencies. Ensuring that information about a research breakthrough is easily available, reaches the appropriate persons and organizations, and that policies and standard-of-care practices for Federally-sponsored programs are modified to reflect the new standard, will require a continued high level of cooperation and coordination among Public Health Service Agencies.

Improved information dissemination efforts are also needed in the area of primary prevention models. As noted in the prevention section, good models of effective prevention interventions have been developed, but often this valuable information is not reaching those persons developing, implementing, and evaluating prevention programs. Here again, the Public Health Service must take the lead in

***The National Strategy for HIV and AIDS***  
***Draft for Office of National Drug Control Policy Review: 6.11.96***

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ensuring that information that can be used to stem the tide of new infections reaches those who can make a difference.

## **CIVIL RIGHTS**

One of the Nation's common goals is to ensure that treatment of persons living with HIV is caring, ethical, and in accordance with legal standards. Discrimination based on HIV status is illegal and morally wrong.

Discrimination undermines the Nation's efforts to prevent and treat HIV infection and bring the epidemic under control. Because of fear of discrimination and stigma, many people do not voluntarily seek testing for HIV, remain unaware of their HIV status, consequently do not take advantage of care that could help them live longer, healthier lives. In addition, opportunities to educate people are lost. Discrimination can also wrongfully deny persons access to housing, employment, and health care.

The Federal government and some States have enacted laws that protect persons with HIV from discrimination on the basis of their infection. Many of the more common legal issues faced by people living with HIV and AIDS, such as family law issues, estate planning, landlord/tenant problems are regulated by State law.

The primary source of Federal statutory protection for people living with HIV is the Americans with Disabilities Act of 1990 (ADA). (Federal Agencies are prohibited from discriminating against people with disabilities under the Rehabilitation Act of 1973.) Title I of the ADA prohibits discrimination against qualified disabled

individuals in employment settings. The Equal Employment Opportunity Commission (EEOC) is responsible for enforcing Title I. Title II of the ADA prohibits discrimination on the basis of disability with regard to public services while Title III prohibits discrimination on the basis of disability in public accommodations. The Department of Justice (DOJ) is responsible for enforcing Titles II and III. The Health Care Financing Administration (HCFA) also enforces regulations regarding the treatment of HIV-infected persons.

## **Opportunities for Progress**

**Enforcement of Federal Laws.** The Federal government has aggressively and successfully prosecuted private sector violations of the ADA. These efforts will continue. Under this provision the government has been extremely successful in prosecuting a range of cases, including clinicians who have refused to care for HIV-positive patients and employers who have dismissed persons based on their actual or perceived HIV status. In addition to ongoing efforts, a joint Department of Justice and Health and Human Services program will seek to combat nursing home discrimination against persons living with AIDS.

**Federal Policies.** The Federal government must also actively work to remedy any of its own existing discriminatory policies. The Director of the Office of National AIDS Policy is working with Federal Agencies to ensure that HIV testing programs follow the recommendations of public health

professionals. The Administration will also continue to oppose Congressional attempts to force discharge of infected military personnel who are still able to serve their country.

**Leadership.** The United States has made progress in fighting discrimination. However, the enactment of laws is insufficient to end discrimination. As a Nation we need to be vigilant and vocal in our efforts to fight discrimination. This is a responsibility that must be shared among Federal Agencies, States, communities, and the citizens of this country.

***The National Strategy for HIV and AIDS***  
***Draft for Office of National Drug Control Policy Review: 6.11.96***

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***Footnotes***

1. *Morbidity and Mortality Weekly Report*. U.S. Department of Health and Human Services, Public Health Service. November 24, 1995, vol. 44, No. 46.
2. Communication, Department of Labor.
3. For 5 years of care after initial heart attack. Source: *American Journal of Cardiology*, 1990.
4. Depending on stage diagnosed -- early or late. Source: Swartz & Rollins, *Business and Health*, 1985, 85, 24-6.
5. *Journal of the American Medical Association*, July 28, 1993.
6. The Public Health Service Agencies within DHHS with responsibility for a range of activities and programs associated with the HIV epidemic are: the National Institutes of Health (NIH), the Centers for Disease Control and Prevention (CDC), the Substance Abuse and Mental Health Services Administration (SAMSHA), the Health Resources and Services Administration (HRSA), the Agency for Health Care Policy and Research (AHCPR), the Food and Drug Administration (FDA), and the Indian Health Service (IHS). Information regarding these agencies can be found in the Appendices.
7. Public Health Service Plan for the Prevention and Control of Acquired Immune Deficiency Syndrome (AIDS), Public Health Reports 100:453-455, September-October, 1985.
8. Coolfont Report. A PHS plan for the Prevention and Control of AIDS and the AIDS Virus. Public Health Reports 101:341-348, July-August 1986.
9. Report of the Second Public Health Service AIDS Prevention and Control Conference. Public Health Reports. Vol. 103 Supplement No.1 (Revised). 1988.
10. The Public Health Service Strategic Plan to Combat HIV & AIDS in the United States. U.S. Department of Health and Human Services. 1992.
11. AIDS: An Expanding Tragedy. The Final Report of the National Commission on AIDS. Washington, DC. 1993.

***The National Strategy for HIV and AIDS***  
***Draft for Office of National Drug Control Policy Review: 6.11.96***

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12. This section will address primary prevention activities. Other aspects of prevention, such as secondary prevention (i.e., preventing complications of HIV infection), development of topical microbicides, the behavioral components of vaccine research, and international prevention activities will be discussed in the following research, care and services, and international activities sections.

13. External Review of HIV Prevention Strategies by the CDC Advisory Committee on the Prevention of HIV Infection. U.S. Department of Health and Human Services, Public Health Service. June 1994.

14. Information on NIH-supported behavioral and epidemiological research relevant to primary prevention can be found in Appendix B: Research.

15. *AIDS and Behavior: An Integrated Approach*. Judith D. Auerbach, Christina Wypijewska, and H. Keith H. Brodie, Editors. Institute of Medicine, National Academy Press, Washington, D.C., 1994. p.79.

16. *AIDS and Behavior: An Integrated Approach*. Judith D. Auerbach, Christian Wypijewska, and H. Keith H. Brodie, Editors. Institute of Medicine. National Academy Press. Washington, DC. 1994.

17. *AIDS and Behavior: An Integrated Approach*. Judith D. Auerbach, Christian Wypijewska, and H. Keith H. Brodie, Editors. Institute of Medicine. National Academy Press. Washington, DC. 1994.

18. JAMA article used in PRIM&R speech

19. Don C. Des Jarlais, Holly Hagan, Samuel R. Friedman, Patricia Friedmann, David Goldberg, Martin Frischer, Steven Green, Kerstin Tunving, Bengt Ljungberg, Alex Wodak, Michael Ross, David Purchase, Margaret E. Millson, Ted Myers. Maintaining Low HIV Seroprevalence in Populations of Injecting Drug Users. JAMA, October 18, 1995 -- Vol. 274, No. 15. pp 1226-1231.

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21. Maria Wawer, Science. 9.08.95, vol. 269, No. 5229

22. Personal communication from CDC Division TB Elimination.

***The National Strategy for HIV and AIDS***  
***Draft for Office of National Drug Control Policy Review: 6.11.96***

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23. Alan B. Stone, and Penelope J. Hitchcock. Vaginal Microbicides for Preventing the Transmission of HIV. *AIDS* 1994, 8 (suppl 1):S285-S293.

24. The accelerated approval regulation permits companies to seek approval of drugs for serious or life-threatening diseases when the drug provides meaningful therapeutic benefit over existing therapies. Under these procedures, the FDA may approve drugs based on surrogate endpoints, such as CD4+ cell counts that reasonably predict that a drug provides clinical benefit. The company is then required to confirm this clinical benefit through additional human studies to be completed after marketing approval. The accelerated approval regulation provides for removal of the drug from the market if further studies do not confirm the clinical benefit of the therapy.

25. Housing and the HIV/AIDS Epidemic: Recommendations for Action. National Commission on AIDS. Washington, D.C. July 1992.

26. *HIV/AIDS Policy Guidance*. U.S. Agency for International Development. September 1995.

27. Until recently, the United Nations' response to HIV/AIDS was carried out primarily by the World Health Organization's Global Programme on AIDS. On January 1, 1996 the U.N. launched UNAIDS, co-sponsored by six U.N. agencies to strengthen coordination and focus support for HIV/AIDS activities at the global and country levels. UNAIDS has established three mutually reinforcing roles: to be a major source of policy development and research; provide technical support; and be an advocate for comprehensive, multisectoral responses to the pandemic.

28. Douglas S. Paauw, Marjorie D. Wenrich, J. Randall Curtis, Jan D. Carline, Paul G. Ramsey. Ability of Primary Care Physicians to Recognize Physical Finding Associated with HIV Infection. *JAMA*. 1995; 274:1380-1382.

29. Colombotos, J., Messeri, P., McConnell, M.B., et al: Physicians, Nurses, and AIDS: Findings From a National Study. Rockville, MD: Agency for Health Care Policy and Research; 1995. Grant No. HS06359. (NTIS Publication PB95-129185)

***III. APPENDICES***

***ONDCP Appendix***

## **TREATMENT**

**Agency:** Office of National Drug Control Policy

**Goal:** Reduce the number of current hardcore drug addicts.

**Objective:** Reduce the number of injection drug use and cocaine addicts with high risk sex practices 20 percent by 1997.

**What the base figure the 20 percent reduction is based on?**

**Action Steps:** Encourage private sector drug treatment organizations to share information and work together to heighten treatment efforts nationwide, including efforts aimed and HIV/AIDS treatment.

Encourage community-based treatment services in all communities to include services for drug use and HIV/AIDS.

Support state organizations in providing a statewide network of community treatment partnerships.

Convene a forum to address national treatment policy matters, including the connection between HIV/AIDS and drug use.

Provide guidelines on ??? to communities receiving Substance Abuse Performance Partnership funds.

**Descriptions:** Substance Abuse Performance Partnership Program. In addition, ONDCP's annual National Drug Control Strategy includes treatment of illicit drug use related to co-morbid disorders such as HIV/AIDS.

**FY 95:** \$1,600,000

**FY 96:** \$1,600,000 **Does the \$1.6 million cover both treatment and prevention? Or is the total for both treatment and prevention \$3.2 million?**

**Is this program co-funded with any other departments or agencies?**

**Populations Served:** 2.7 million, at risk. **Are these persons enrolled in ONDCP-sponsored**

programs?

**Constituency Involvement:** Community partnerships. Any examples of groups involved?

**Unmet Need:** Reduction plan targets approximately 20 percent of the population during the coming fiscal year. Twenty percent of which population?

## **PREVENTION**

**Agency:** Office of National Drug Control Policy

**Goal:** Reduce the number of new hardcore drug addicts.

**Objective:** Reduce the number of injection drug use and cocaine addicts with high risk sex practices 20 percent by 1997.

**What the base figure the 20 percent reduction is based on?**

**Action Steps:** Encourage private sector drug treatment organizations to share information and work together to heighten treatment efforts nationwide, including efforts aimed and HIV/AIDS treatment.

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*Draft for Office of National Drug Control Policy Review: 6.11.96*

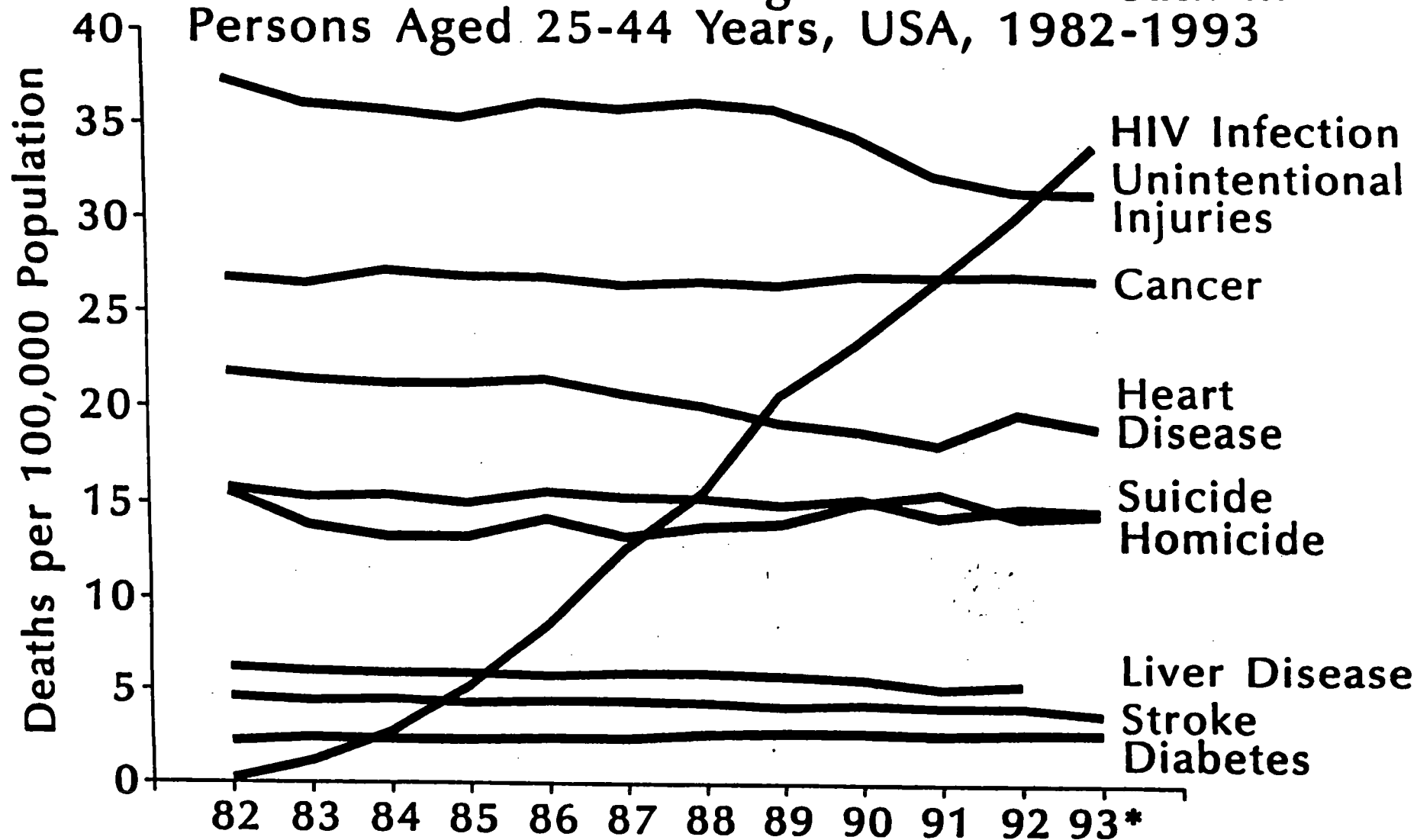
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**Unmet Need:** Reduction plan targets approximately 20 percent of the population during the coming fiscal year. Twenty percent of which population?

***IV. FIGURES, ACRONYMS, AND MEMBERS OF THE INTERDEPARTMENTAL TASK  
FORCE ON HIV AND AIDS***

***Figure 1***      Death Rates from Leading Causes of Death in Persons Aged 25-44 Years,  
USA, 1982 -1993

# Death Rates from Leading Causes of Death in Persons Aged 25-44 Years, USA, 1982-1993



National Vital Statistics

\*Provisional data

CDC

***The National Strategy for HIV and AIDS***  
***Draft for Office of National Drug Control Policy Review: 6.11.96***

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***Figure 2*** Cumulative U.S. AIDS Cases: 2/83 through 12/94

# **Cumulative U.S. AIDS Cases as of 2/83 N~1,000**



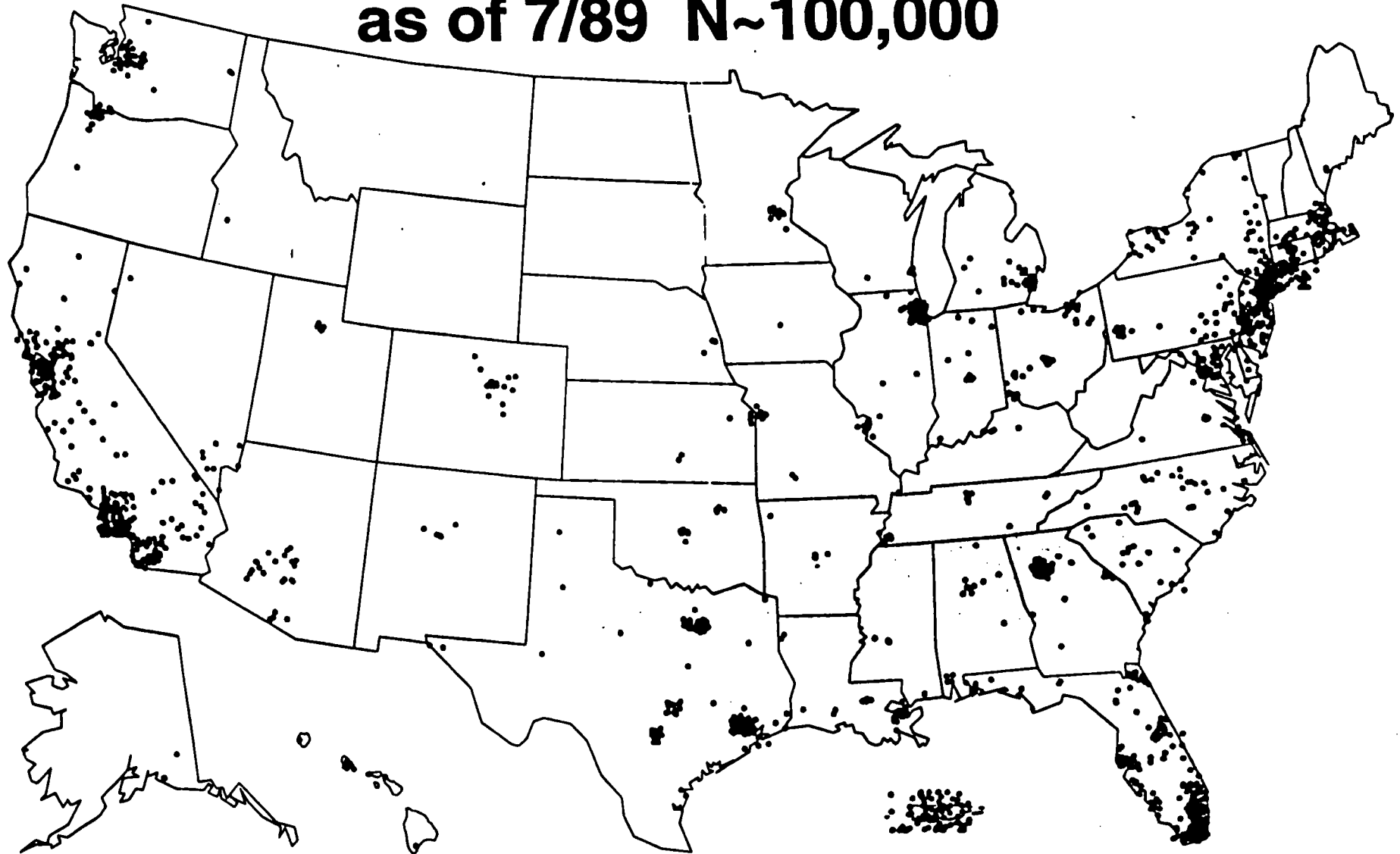
Each point = 30 cases

# **Cumulative U. S. AIDS Cases as of 5/85 N~10,000**



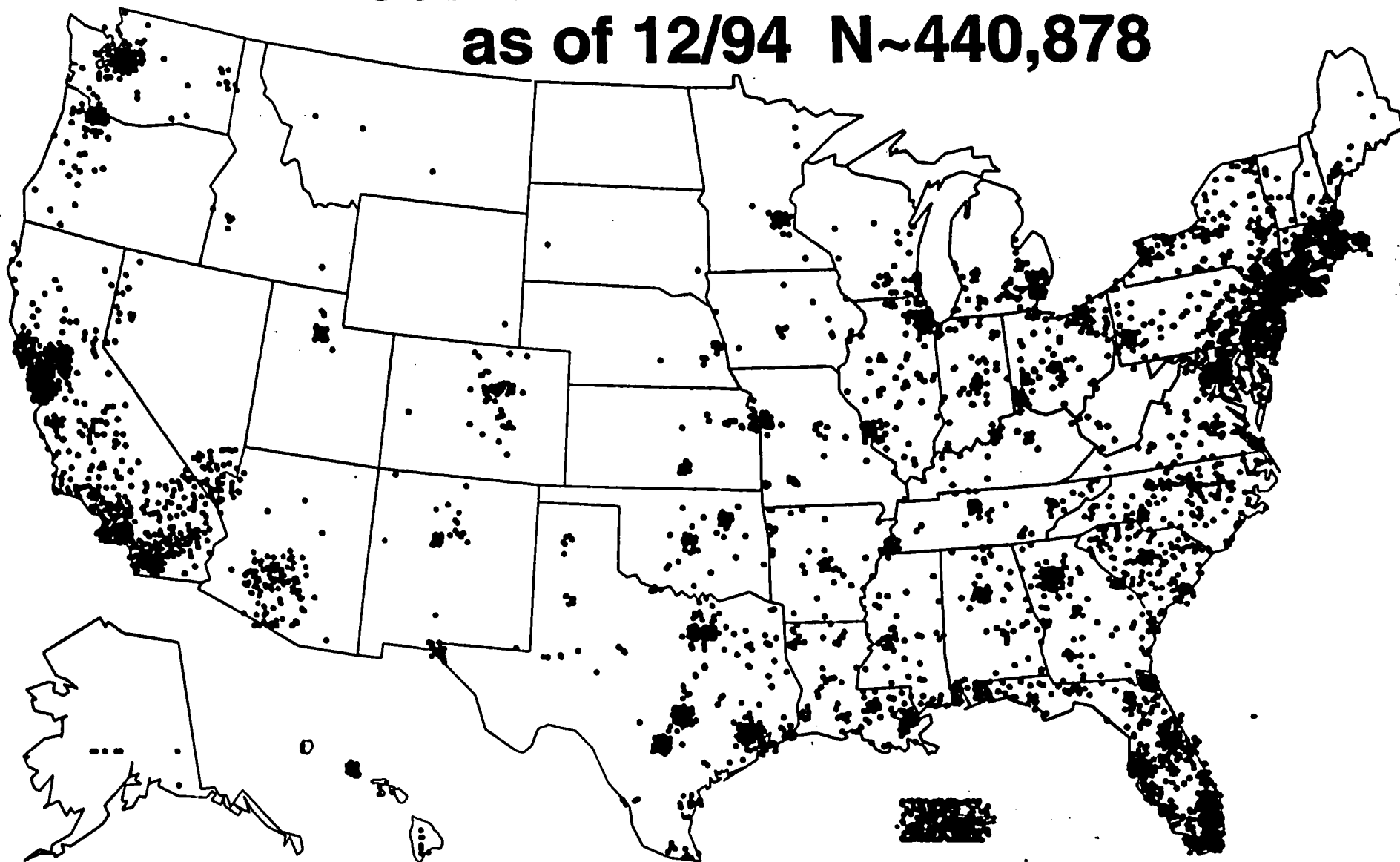
**Each point = 30 cases**

# **Cumulative U.S. AIDS Cases as of 7/89 N~100,000**



**Each point = 30 cases**

# Cumulative U. S. AIDS Cases as of 12/94 N~440,878



Each point = 30 cases

***The National Strategy for HIV and AIDS***  
***Draft for Office of National Drug Control Policy Review: 6.11.96***

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***Acronym List***

|       |                                                                  |
|-------|------------------------------------------------------------------|
| ACTG  | AIDS Clinical Trial Group                                        |
| ADA   | Americans with Disabilities Act of 1990                          |
| ADC   | AIDS Dementia Complex                                            |
| ACTIS | AIDS Clinical Trials Information Service                         |
| ADAP  | AIDS Drug Assistance Programs                                    |
| AETC  | AIDS Education Training Center                                   |
| AHCPR | Agency for Health Care Policy and Research                       |
| AIDS  | Acquired Immune Deficiency Syndrome                              |
| AOD   | Alcohol and other drugs                                          |
| ASO   | AIDS Service Organization                                        |
| ATIS  | HIV/AIDS Treatment Information Service                           |
| ATOD  | Alcohol, tobacco, and other drugs                                |
| AZT   |                                                                  |
|       |                                                                  |
| BOP   | Bureau of Prisons                                                |
| BRTA  | Business Responds to AIDS                                        |
|       |                                                                  |
| CARE  | Ryan White Comprehensive AIDS Resources Emergency Act            |
| CDBG  | Community Development Block Grant                                |
| CDC   | The Centers for Disease Control and Prevention                   |
| CMV   | Cytomegalovirus                                                  |
| CNS   | Central Nervous System                                           |
| CPCRA | Terry Beirn Community Programs for Clinical Research on AIDS     |
|       |                                                                  |
| DEA   | Drug Enforcement Agency                                          |
| DHHS  | Department of Health and Human Services                          |
| DOD   | Department of Defense                                            |
| DOJ   | Department of Justice                                            |
| DOL   | Department of Labor                                              |
|       |                                                                  |
| EDC   | Educational Development Center                                   |
| EEOC  | Equal Employment Opportunity Commission                          |
| ENFPA |                                                                  |
|       |                                                                  |
| FDA   | Food and Drug Administration                                     |
| FBI   | Federal Bureau of Investigation                                  |
|       |                                                                  |
| GCRC  | General Clinical Research Centers Program                        |
| GIPA  | Greater Involvement of Persons Infected and Affected by HIV/AIDS |

***The National Strategy for HIV and AIDS***  
***Draft for Office of National Drug Control Policy Review: 6.11.96***

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|       |                                                              |
|-------|--------------------------------------------------------------|
| HCFA  | Health Care Financing Administration                         |
| HIV   | Human Immunodeficiency Virus                                 |
| HOPWA | Housing Opportunities for Persons with AIDS                  |
| HRSA  | Health Resources and Services Administration                 |
| HSV   | Herpes Simplex Virus                                         |
| HUD   | Department of Housing and Urban Development                  |
| ICD   | Institute(s), Center(s), Division(s)                         |
| IDTF  | Interdepartmental Task Force on HIV and AIDS                 |
| IHS   | Indian Health Service                                        |
| INS   | Immigration and Naturalization Service                       |
| IOM   | Institute of Medicine                                        |
| JMD   | Justice Management Division                                  |
| LRTA  | Labor Responds to AIDS                                       |
| MAC   | <i>Mycobacterium Avium</i> Complex                           |
| NCRR  | National Center for Research Resources                       |
| NGO   | Non-governmental Organization                                |
| NIDA  | National Institute on Drug Abuse                             |
| NIH   | National Institutes of Health                                |
| NREN  | National Research and Education Network                      |
| NVC   | National Victims Center                                      |
| OAR   | Office of AIDS Research                                      |
| OI    | Opportunistic Infection                                      |
| OMB   | Office of Management and Budget                              |
| ONAP  | Office of National AIDS Policy                               |
| PAC   | Presidential Advisory Council on HIV and AIDS                |
| PCP   | <i>Pneumocystis carinii</i> pneumonia                        |
| PHS   | Public Health Service                                        |
| PLWH  | Persons living with HIV                                      |
| PSA   | Public Service Announcement                                  |
| PVO   | Private Voluntary Organization                               |
| PWA   | Person with AIDS                                             |
| RFIP  | Research Facilities Infrastructure Program (NIH)             |
| RPRC  | Regional Primate Research Center (NIH)                       |
| RWCA  | Ryan White Comprehensive AIDS Resources Emergency (CARE) Act |

***The National Strategy for HIV and AIDS***  
***Draft for Office of National Drug Control Policy Review: 6.11.96***

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|        |                                                           |
|--------|-----------------------------------------------------------|
| SAMHSA | Substance Abuse and Mental Health Services Administration |
| SPF    | Specific Pathogen-Free                                    |
| SPNS   | Special Projects of National Significance                 |
| SSA    | Social Security Administration                            |
| SSI    | Supplemental Security Income                              |
| STD    | Sexually transmitted disease                              |
| STI    | Sexually transmitted infection                            |
| TA     | Technical Assistance                                      |
| TB     | <i>Mycobacterium tuberculosis</i>                         |
| UNAIDS | United Nations Programme on AIDS                          |
| UNDP   |                                                           |
| UNICEF |                                                           |
| USAID  | U.S. Agency for International Development                 |
| USIA   | U.S. Information Agency                                   |
| USMS   | U.S. Marshals Service                                     |
| VA     | Department of Veterans Affairs                            |
| WHO    | World Health Organization                                 |

## **TREATMENT**

**Agency:** Office of National Drug Control Policy

**Goal:** Reduce the number of current hardcore drug addicts.

**Objective:** Reduce the number of injection drug use and cocaine addicts with high risk sex practices 20 percent by 1997.

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**FY 96:** \$1,600,000 **Does the \$1.6 million cover both treatment and prevention? Or is the total for both treatment and prevention \$3.2 million?**

**Is this program co-funded with any other departments or agencies?**

**Populations Served:** 2.7 million, at risk. **Are these persons enrolled in ONDCP-sponsored**

programs?

**Constituency Involvement:** Community partnerships. Any examples of groups involved?

**Unmet Need:** Reduction plan targets approximately 20 percent of the population during the coming fiscal year. Twenty percent of which population?

## **PREVENTION**

**Agency:** Office of National Drug Control Policy

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## **TREATMENT**

**Agency:** Office of National Drug Control Policy

**Goal:** Reduce the number of current hardcore drug addicts.

**Objective:** Reduce the number of injection drug use and cocaine addicts with high risk sex practices 20 percent by 1997.

**What the base figure the 20 percent reduction is based on?**

**Action Steps:** Encourage private sector drug treatment organizations to share information and work together to heighten treatment efforts nationwide, including efforts aimed and HIV/AIDS treatment.

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