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Subgroup/Office of Origin:	National AIDS Policy Office
Series/Staff Member:	Patsy Fleming
Subseries:	National AIDS Strategy

OA/ID Number:	9005
FolderID:	

Folder Title:
7/15/ 96 Strategy Comments [1]

Stack:	Row:	Section:	Shelf:	Position:
S	66	5	8	3

THE WHITE HOUSE
WASHINGTON

GOODNEWS ✓

To Jane
Date 7/17/96 Time 11:00 am

WHILE YOU WERE OUT
M Bundy Mancini
of Treasury
Phone (202) 6220059
Area Code Number Extension

TELEPHONED	☒	PLEASE CALL	☐
CALLED TO SEE YOU	☐	WILL CALL AGAIN	☒
WANTS TO SEE YOU	☐	URGENT	☐

RETURNED YOUR CALL ☐

Message Good news. She's
handled the problem.
Faxing back piece on
banking (internatl) it went to
their office of Internatl Affairs.
Comments are included.
Awaiting piece from their

when tax policy piece is back to her.



AMPAD
EFFICIENCY®

23023

CARBONLESS



DEPARTMENT OF THE TREASURY
WASHINGTON, D.C. 20220

FAX TRANSMITTAL SHEET

DATE: 7-17-96

NUMBER OF SHEETS TO FOLLOW: _____

TO: Jane Sanville

ADDRESSEE'S FAX #: 632-1096

ADDRESSEE'S CONFIRMATION #: _____

FROM: Sandy Mancini

SENDER'S FAX #: 202-622-0073

SENDER'S CONFIRMATION #: 202-622-1700

SPECIAL INSTRUCTIONS/COMMENTS:

Our last attachment. Thanks, Sandy.
Call if you need any help.

07/13/96 MON 17:53 FAX 2026321090

RESEARCH

Agency: Department of the Treasury

Goal: Through tax code policies, provide incentives for privately-sponsored research, including HIV-related research.

Objective: Encourage private sector investment in medical research, including HIV-related research.

Action Steps: Support ~~permanent~~ *the revenue neutral* extension of the Research and Experimentation Tax Credit and the Orphan Drug Tax Credit.

Descriptions: Research and Experimentation (R&E) Tax Credit and Orphan Drug Tax Credit.

FY 95: Not applicable.

FY 96: Not applicable.

FY 97: Not applicable.

Populations Served: Private sector entities supporting research.

Constituency Involvement: The National AIDS Drug Development Task Force, comprised of industry and government representatives and patient advocates, supported these policies.

Unmet Need: 



DEPARTMENT OF THE TREASURY
WASHINGTON, D.C. 20220

FAX TRANSMITTAL SHEET

DATE: 7-17-96

NUMBER OF SHEETS TO FOLLOW: _____

TO: JANE SANVILLE

ADDRESSEE'S FAX #: 632-1096

ADDRESSEE'S CONFIRMATION #: _____

FROM: SANDY MANCINI

SENDER'S FAX #: 202-622-0073

SENDER'S CONFIRMATION #: 202-622-1700

SPECIAL INSTRUCTIONS/COMMENTS:

Here is half of what you are looking for.
Tax Policy is working on the other
attachment you sent to us. I hope you
can read the writing. If you can't, give
me a call.

Thanks

Sandy

622-0059

INTERNATIONAL ACTIVITIES

Agency: Department of the Treasury

international health

Goal: Support, developing ~~world~~ programs, including HIV-related programs.

Objective: Work with the *multilateral development banks* World Bank and ~~IMF~~ to provide large-scale assistance for health projects, including HIV-related projects.

Action Steps: Through the Department's oversight authority over the *multilateral development banks* World Bank, assist in the provision of external financing for AIDS programs in the developing world.

Descriptions: ~~World Bank funding~~ *policy* ~~technical assistance~~ *OR* ~~OR~~ *OR BOTH* *both?*

FY 95: Not applicable.

FY 96: Not applicable.

FY 97: Not applicable.

Populations Served: Developing countries.

Constituent Involvement:

~~Recipients are actively involved in the decision making process.~~

Unmet Need: ~~See~~

multilateral development bank ~~for~~ provision of direct finance, technical assistance and policy advice; and, MDB coordination of bilateral assistance efforts

and implementation
Recipient countries are actively involved in the preparation of MDB lending and technical assistance programs

primary health and

Sandy Mancini → 7/15
Will Walk it down to them →

Mary Anne

David Rubin. He will
be calling.

**OFFICE OF NATIONAL AIDS POLICY
EXECUTIVE OFFICE OF THE PRESIDENT**

750 17th Street, N.W.
Washington, DC 20503

Phone: 202-632-1090
Fax: 202-632-1096

FACSIMILE COVER SHEET

TO: Sylvia Mathews

FAX NUMBER: 622-~~3~~ 0073

FROM: Jane Sanville

DATE: 7.15.96

PAGES INCLUDING COVER SHEET: ~~3~~ 4

COMMENTS:

Sylvia - We need assistance with this as soon as possible. The National Strategy is going to the printers on 7.22.96.

I will call in follow-up. Thanks for your assistance in advance.

Jane Sanville

THE WHITE HOUSE

WASHINGTON

May 24, 1996

MEMORANDUM FOR THE INTERDEPARTMENTAL TASK FORCE ON HIV/AIDS,
DEPARTMENT OF TREASURY

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

SUBJECT: Update of Budget Figures for the National Strategy for
HIV and AIDS

As you remember, 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.

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. Attached is the final language for the Department of Treasury Appendix (attached). Sections of highlighted text require

Comments are due back to the Office of National AIDS Policy **BY NO LATER THAN MAY 31, 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.

Attachment: Department of Energy Appendix for National
Strategy on HIV and AIDS.

RESEARCH

Agency: Department of the Treasury

Goal: Through tax code policies, provide incentives for privately-sponsored research, including HIV-related research.

Objective: Encourage private sector investment in medical research, including HIV-related research.

Action Steps: Support permanent extension of the Research and Experimentation Tax Credit and the Orphan Drug Tax Credit.

Descriptions: Research and Experimentation (R&E) Tax Credit and Orphan Drug Tax Credit.

FY 95: Not applicable.

FY 96: Not applicable.

FY 97: Not applicable.

Populations Served: Private sector entities supporting research.

Constituency Involvement: The National AIDS Drug Development Task Force, comprised of industry and government representatives and patient advocates, supported these policies.

Unmet Need: ???

INTERNATIONAL ACTIVITIES

Agency: Department of the Treasury

Goal: Support developing world programs, including HIV-related programs.

Objective: Work with the World Bank and MDBs?? to provide large-scale assistance for health projects, including HIV-related projects.

Action Steps: Through the Department's oversight authority over the World Bank, assist in the provision of external financing for AIDS programs in the developing world.

Descriptions: World Bank funding. ^{+policy} technical assistance OR \$ OR both?

FY 95: Not applicable.

FY 96: Not applicable.

FY 97: Not applicable.

Populations Served: Developing countries.

Constituent Involvement: ??? -- Are any of the recipient countries involved in any of the decision-making processes?

Unmet Need: ???

**OFFICE OF NATIONAL AIDS POLICY
EXECUTIVE OFFICE OF THE PRESIDENT**

750 17th Street, N.W.
Washington, DC 20503

Phone: 202-632-1090
Fax: 202-632-1096

FACSIMILE COVER SHEET

7/3 at 10:50 a.m. faxed to
TO: Sandy Mancini

FAX NUMBER: (202) 622-0073

FROM: Sherry Darden for Jane Samille

DATE: July 3, 1996

PAGES INCLUDING COVER SHEET: Five (5)

COMMENTS:

Sandy:

Thanks for your help. Jane is in Vancouver at a Conference. I will let Jane know that you have forwarded her request to Clara Apodaca. Please call me with a phone number and fax for Mrs Apodaca when you get a chance.

Sandy called to say Clara's phone # is 622 0410

measuring

*7/9 talked to Clara
about Jane's instance.
(see back page)*

**OFFICE OF NATIONAL AIDS POLICY
EXECUTIVE OFFICE OF THE PRESIDENT**

750 17th Street, N.W.
Washington, DC 20503

Phone: 202-632-1090
Fax: 202-632-1096

FACSIMILE COVER SHEET

TO: SYLVIA MATHEWS, Dept of Treasury

FAX NUMBER: 622-0073

FROM: JANE SANVILLE

DATE: 5-23-96

PAGES INCLUDING COVER SHEET: 4

COMMENTS:

6/21 Sylvia Mathews 622-1906
left message & secretary to call

6/27
No answer.

sent 9:47

May 23, 1996

MEMORANDUM FOR THE INTERDEPARTMENTAL TASK FORCE ON HIV/AIDS,
DEPARTMENT OF TREASURY

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

SUBJECT: Update of Budget Figures for the National Strategy for
HIV and AIDS

As you remember, 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.

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. Attached is the final language for the Department of Treasury Appendix (attached). **Information that was missing or unclear in your original submission has been 'redlined'; please be certain to provide this information in your response.**

Comments are due back to the Office of National AIDS Policy **BY NO LATER THAN MAY 31, 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.

Attachment: Department of Treasury Appendix for National
Strategy on HIV and AIDS.

RESEARCH

Agency: Department of the Treasury

Goal: Through tax code policies, provide incentives for privately-sponsored research, including HIV-related research.

Objective: Encourage private sector investment in medical research, including HIV-related research.

Action Steps: Support permanent extension of the Research and Experimentation Tax Credit and the Orphan Drug Tax Credit.

Descriptions: Research and Experimentation (R&E) Tax Credit and Orphan Drug Tax Credit.

FY 95: Not applicable.

FY 96: Not applicable.

FY 97: Not applicable.

Populations Served: Private sector entities supporting research.

Constituency Involvement: The National AIDS Drug Development Task Force, comprised of industry and government representatives and patient advocates, supported these policies.

Unmet Need: ???

INTERNATIONAL ACTIVITIES

Agency: Department of the Treasury

Goal: Support developing world programs, including HIV-related programs.

Objective: Work with the World Bank and MDBs?? to provide large-scale assistance for health projects, including HIV-related projects.

Action Steps: Through the Department's oversight authority over the World Bank, assist in the provision of external financing for AIDS programs in the developing world.

Descriptions: World Bank funding.

FY 95: Not applicable.

FY 96: Not applicable.

FY 97: Not applicable.

Populations Served: Developing countries.

Constituent Involvement: ??? -- Are any of the recipient countries involved in any of the decision-making processes?

Unmet Need: ???



DEPARTMENT OF HEALTH AND HUMAN SERVICES
WASHINGTON, D.C. 20201

EXECUTIVE SECRETARIAT

FACSIMILE

PLEASE NOTIFY OR HAND-CARRY THIS TRANSMISSION
TO THE FOLLOWING PERSON AS SOON AS POSSIBLE:

NAME:

Jane Sanville

ADDRESS:

MESSAGE:

SAMSHA FDA
HRSA AHCPR
ASL
OGC
CDC
HCFA - Same
Comments
as earlier
letter

FAX NUMBER:

632 - 1096

Missing

OFFICE NUMBER:

632 - 1090

FROM:

GLEN HARELSON
POLICY COORDINATOR

IHS

ACF

OPA

DIH

FAX NUMBER:

202 690-7203

OFFICE NUMBER:

202 690-7699

NUMBER OF PAGES (INCLUDING THIS ONE): 29

JUN-27-96 THU 15:57

FAX NO. 4431450

P. 03



DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

JUN 27 1996

Substance Abuse and Mental
Health Services Administration
Rockville MD 20857

TO: Executive Secretariat, OS

FROM: Administrator, SAMHSA

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

Thank you for the opportunity to respond to the draft National Strategy for HIV/AIDS. The following represent suggested changes, and/or additions that should be included in the document.

INTRODUCTION**An Expanding Public Health Threat, pg. 7**

✓ Include in the second paragraph, third sentence of this section, "Among the populations being more and heterosexual injecting drug users and their partners as well as non-injecting drug users (i.e., crack/cocaine, alcohol).

PREVENTION**Opportunities for Progress****Modes of Transmission, pg. 18**

✓ Include in the first paragraph, second sentence, "Recent epidemiologic data show that the HIV epidemic continues to spread in the United States among people who engage in injection drug use, which includes the sharing of drug paraphernalia, and/or having sex with an injecting drug user, young and minority men....."

✓ Include in the same paragraph, after the following sentence, "As of October 1995, African Americans...Hispanics represented 18 percent of new cases. Over 50 percent of women with HIV/AIDS are African American and Hispanic.

Substance Abuse Prevention and Treatment, pg. 22

✓ Revise the first paragraph, first sentence to read, "Injection drug is...one third of all new cases directly or....." (Deleted 'are')

✓ Revise the second paragraph, last sentence to read, "It is vital to continue and strengthen efforts to integrate...."

✓ Revise the third paragraph, first sentence to read, "A second avenue for controlling the spread of HIV among substance abusers is"

✓ Following fourth paragraph, include, "SAMHSA endorses the urgent need for the integration of substance abuse prevention/treatment and HIV prevention services for those who use

2nd
page
SAMHSA
missing

HRSA Comments

HRSA	Increase the number of competent primary care providers willing to care for HIV positive persons	~~\$16,300,000~~ 284	~~\$16,300,000~~ ✓12,000,000	✓14,287,000
	Reduce barriers to obtaining dental care for HIV positive persons	~~\$6,937,000~~	~~\$6,937,000~~	✓6,937,000
	Increase access to care and improve quality of life for persons living with HIV/AIDS	~~\$632,965,000~~ I: 356,500,000 II: 198,147,000 III: 52,318,000 IV: 26,000,000	~~738,465,000~~ ✓723,465,000 I: 407,000,000 II: 221,897,000 III: 62,568,000 IV: 32,000,000	807,465,000 423,943,000 284,954,000 64,568,000 34,000,000
	Develop and evaluate innovative models of comprehensive managed care for persons living with HIV	Objective 1: ~~\$2,092,302~~ 1,500,000 Objective 2: ~~\$4,000,00~~	Objective 1: ~~\$4,000,00~~ 1,500,000 Objective 2: ~~\$4,000,00~~	1,500,000 1
	Reduce the perinatal transmission of HIV	\$1,520,000	\$1,800,000	1,890,000

96

391,700,000
260,847,000
56,918,000
29,000,000

(1,800,000)(1.05)=

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

✓ ASL
comments

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 1992.² 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 disease³, \$25,000 to \$4,000 for Cancer⁴, and \$119,000 for HIV/AIDS⁵. 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. ~~HHS - 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.

✓ Should point out that lower cancer/heart costs may be attributable to their switching an older, more frail generation

Didn't update figures



DEPARTMENT OF HEALTH & HUMAN SERVICES

Office of the Secretary

The General Counsel
Washington, D.C. 20201

June 24, 1996

NOTE TO GLEN HARELSON

Re: Revised Draft of the National Strategy for HIV and AIDS

We have reviewed the revised draft of the national strategy for HIV and AIDS and have comments on the civil rights portion (pages 42 and 43). We have the following comments regarding the fourth paragraph on page 42 as follows:

1. The Rehabilitation Act of 1973 prohibits discrimination not only by federal agencies but also by recipients of federal funds. This Department shares responsibility for enforcing this law. The first and third sentences address the ADA. We suggest that the second sentence, which discusses the Rehabilitation Act, be moved to the end of the discussion of the ADA; just before "[t]he Health Care Financing Administration." We recommend changing this sentence and adding a new sentence as follows:

✓ Federal agencies and recipients of federal funds are prohibited from discriminating against persons with disabilities under Section 504 of the Rehabilitation Act. DHHS' OCR is responsible for enforcing Section 504 as it pertains to recipients of DHHS funds such as hospitals, nursing homes and social service agencies.

2. This Department has been given responsibility for implementing portions of Title II of the ADA. We suggest that the sentence regarding DOJ's Title II and III enforcement responsibility be followed with language such as the following:

✓ The Department of Health and Human Services' (DHHS) Office for Civil Rights (OCR) is responsible for investigating and resolving Title II complaints of discrimination by health care and social service programs.


Harriet S. Rabb

CDC Comments on National Strategy for HIV/AIDS

Thank you for the opportunity to review the draft *National Strategy for HIV/AIDS*. Our comments are provided below (word changes and additions are indicated in italics).

Budget Tables for CDC (no page number provided):

The figures for 1995 and 1996 have been updated to reflect the most current budget data and figures based on the FY 1997 President's Budget have been provided. (See attached table)

Page 7:

Paragraph 2.

- ✓line 1: delete October; insert *December*
- ✓line 3: delete 501,310; insert 513,486
- ✓line 4: delete 311,381; insert 319,849
- ✓line 11: delete 1994; insert 1995
- ✓lines 12, 13: delete 81,000; revise sentences to read *74,000 new cases of AIDS were reported to CDC. More than 46,000 AIDS related deaths were reported to the CDC in 1994.*

Paragraph 3.

- ✓line 15: delete 1994, more than; insert 1995, *neary*
- ✓line 21: delete 1994. alone. more than; insert 1995, *approximately 800*

Paragraph 4.

- ✓line 3: revise to read....occur among young people.

Page 8:

- ✓top of page: delete "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, more than two young people every hour." (We have no data to support this sentence).

Paragraph 1.

- ✓line 3: delete "As of October 1995; insert *in 1995,*
- ✓line 4: delete 38; insert 40
- ✓lines 8, 9: delete 18; insert 19; delete new cases reported through October; insert cases reported in 1995
- ✓line 12: delete October; insert *December*
- ✓line 13: delete 51; insert 52
- ✓lines 14-17: we have been unable to locate support for this sentence.

Paragraph 2.

- ✓line 5: revise to read between January 1993 and December 1995

SENT BY:

7- 2-96 : 4:56PM :

CDC/EXEC SEC-

202 690 7203:# 4/ 5
CDC/EXEC SEC:# 4/ 5

HIVRATPL.COM

Page 31

Healthy People 2000 Objectives (as displayed in Healthy People 200 Midcourse Review and 1995 Revisions). The information currently listed was developed during CDC's 1991-1992 HIV Strategic planning process and although still relevant, will be updated later this year in a new strategic planning activity. If the Appendix section remains as is, we recommend the following changes:

Page 3:

✓ Budget table, FY 1995 \$141,046,000; FY 1996 \$139,668,000; FY 97 \$139,778,000

Page 6:

✓ Budget tables, FY 1995 \$45,960,000; FY 1996 \$45,512,000; FY 1997 \$45,647,000

Page 7:

✓ Goal: line 2, delete persons; insert youth

✓ Objectives: line 3, revise to read part of comprehensive school health education.

✓ Action Steps: line 2, delete programs, change acronym to (CSHEs); line 6, delete students, insert age youth

Page 8:

✓ line 2, revise CSHEPs to CSHPs

✓ line 16, delete and colleges and universities

✓ line 17 revise to read.....within CSHEs.

✓ line 19, delete coordinators, insert directors

Page 9:

✓ line 7, revise to read.....national non-governmental organizations.....

✓ Budget table: FY 1995 \$48,205,000; FY 96 \$47,735,000; FY 97 \$47,771,000

✓ Constituency Involvement, line 5, revise to read.....agency, District of Columbia, six territorial education agencies,.....

Page 11:

✓ Budget table: FY 1995 \$185,625,000; FY 96 \$183,814,000; FY 98 \$203,958,000

Page 14:

✓ Budget table: FY 1995 \$168,995,000; FY 96 \$167,351,000; FY 97 \$181,027,000

✓ lines 13, 14: revise to read Puerto Rico, Guam and the U.S. territories.

Page 16,

Paragraph 1:

✓ line 13: should \$ 6.848 million be changed to \$ 6.85 billion?

Page 17:

Paragraph 2,

✓ line 12: American should be *Americans*

Paragraph 3,

line 14: delete Centers for Disease Control and Prevention and insert CDC. (The acronym was previously defined in paragraph 2).

Page 18:

Paragraph 3,

✓ lines 21, 22: delete As of October; insert *In 1995*,

✓ line 23: delete 38; insert 40; delete newly

✓ line 24: delete 18; insert 19

Page 22:

Insert before section on "Treatment for Sexually Transmitted Disease and Tuberculosis":

✓ In addition, during a December 8, 1995, White House meeting on AIDS, President Clinton called for a national meeting of state and local health officials from the fields of public health and drug abuse prevention to develop an action plan that more effectively integrates HIV prevention and substance abuse prevention. In response to this call for action, CDC, HRSA, NIDA, and SAMSHA have worked together to jointly cosponsor and plan the Forum.

Page 25:

format
Section titled "Research" - Most of the focus here is on biomedical research. To simply label this section "Research" seems to imply that all types of research will be discussed, however, behavioral and social science research are not addressed. We suggest that you change to title "Research" to *Biomedical Research*".

CDC Appendix:

As we previously suggested during an earlier review of this draft document, we strongly suggest that the information in this section be replaced with the latest version of the

SENT BY:

7- 2-96 : 4:56PM :

CDC/EXEC SEC-

202 690 7203:# 5/ 5

FY 97

Pres. Budget

FY 95 Actuals FY 96

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.	5141,076,000 4	~~5148,317,000~~ 139,668,000	139,778
	Increase the public understanding of, involvement in, and support for HIV prevention	^{1/2} 545,970,000	~~546,889,000~~ 45,512,000	43,547
	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.	0 548,275,000	~~548,162,000~~ 47,735	47,771
	Prevent or reduce behaviors or practices which place individuals at risk of HIV infection, and for HIV positive individuals, place others at risk.	²⁵ 5185,686,000	~~5289,764,000~~ 183,814	203,958
	Increase individual knowledge of sero-status and strengthen systems for successful referral to early intervention services.	8,995 5169,826,000	~~5179,886,000~~ 167,351	181,027
		581,831,000	584,080	618,081

To be cleared on 7/3 by CDC's financial management office. ... 7/2/96



DEPARTMENT OF HEALTH & HUMAN SERVICES

Health Care
Financing Administration

Memorandum

JUN 26 1996

FROM: Acting Director
Medicaid Bureau

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

TO: Office of National AIDS Policy
Attention: Glen Harelson

We have reviewed the draft of the National Strategy for HIV and AIDS, and wish to include a budget table for the Health Care Financing Administration (HCFA). The following should be added to the Summary Budget Tables:

AGENCY	GOALS	FY 95 Actualities	FY 96	FY 97 President's Budget
HCFA	Develop and implement a campaign to inform HIV-women in selected pilot areas about the benefits of AZT	✓\$50,000 (Federal share)		
	Expand Pilot project to one State in all regions		✓\$60,000 (Federal share)	
	Expansion of project to include all States			✓\$185,000* (Federal share)
	Provide quality health care for home HIV positive Medicaid and Medicare beneficiaries.	✓\$25,000	N/A	N/A

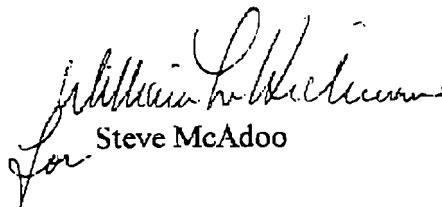
*Subject to availability of funds.

Page 2 - Office of AIDS Policy

Provide primary health care to Medicaid eligible HIV-positive persons.	\$1,640,000,000 (Federal Share)	✓ \$1,800,000,000 (Federal Share)	✓ \$1,970,000,000 (Federal Share)
--	------------------------------------	---	---

In addition, the budget figures reflected above should be inserted on the appropriate pages of the HCFA appendices. On page 3 of the HCFA appendix, the text for unmet need should read, "Since Medicaid is an entitlement program any unmet need is a result of State budgeting limitations."

We appreciate the opportunity to review the draft national strategy for HIV and AIDS. .


For Steve McAdoo

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
Rockville MD 20857

MEMORANDUM

Date: June 26, 1996

To: Patricia S. Fleming
Director, Office of National HIV/AIDS PolicyFrom: Associate Commissioner for AIDS and Special Health Issues
Food and Drug Administration

Subject: Draft of the National Strategy for HIV and AIDS - Comments and Clearance

Thank you for the opportunity to comment on the draft National Strategy for HIV and AIDS document. With the exception of one comment discussed below, the Food and Drug Administration (FDA) concurs with the document. In several sections of the document it states "awaiting revised language from NIH." If any of the revised language directly relates to FDA activities we would like the opportunity to review the revisions.

On page 26, column 2, last paragraph it states: "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." FDA considers accelerated approval only one reason for the faster approval times. We suggest the following revision: "In addition, the Food and Drug Administration, through its expedited review and accelerated approval programs, is now approving drugs faster than ever before and faster than any European nation."

As requested, the FDA budget figures for the appendices are attached. Minor editorial comments are also attached.

If you have any questions, please call me or Donald Pohl of my staff at (301) 443-0104.

Theresa A. Toigo
Theresa A. Toigo, RPh, MBA

Attachments

Attachment I ✓

**Food and Drug Administration
AIDS Funding Level Summary
June 1996**

FDA Appendices	FY 95 Actuals	FY 96 Estimates	FY 97 Presidents Budget Request
Ensure the safety and effectiveness of HIV-related therapeutic agents	\$25,235,000	\$25,235,000	\$25,235,000
Ensure the safety and effectiveness of HIV-related preventive and therapeutic vaccines	\$11,863,000	\$11,863,000	\$11,863,000
Ensure the effectiveness of test methodologies (such as diagnostic reagents and test kits) for HIV detection, confirmation, and viral load measurement	\$8,732,000	\$8,732,000	\$8,732,000
Reduce transfusion-transmitted HIV infection	\$17,458,000	\$17,458,000	\$17,458,000
Ensure the safety and effectiveness of HIV-related medical devices	\$9,457,000	\$9,457,000	\$9,457,000
Totals	\$72,745,000	\$72,745,000	\$72,745,000

Office of AIDS and Special Health Issues
Food and Drug Administration

Attachment II

The National Strategy for HIV and AIDS

Draft for Department of Health and Human Services Review: 6.11.96

Editorial Comments

✓ Page 44, footnote 5 - We should reference the page number for the article.

✓ Page 45, footnote 18 - This footnote lacks the name and date of the article.

Acronym List:

✓ AZT not defined, suggested wording - Retrovir™, zidovudine

✓ ENFPA, UNDP, and UNICEF are also not defined. We do not have any suggested language.

AHCPR
Comments

MEMORANDUM**DATE:****TO:** Director, Office of National AIDS Policy**FROM:** Administrator**SUBJECT:** Review and Comment on Draft of the National
Strategy for HIV and AIDS

This is in response to your request for review of the above referenced document. We have reviewed the document and appendices.

This memorandum transmits corrected budget tables for the Agency for Health Care Policy and Research (AHCPR), showing the FY 1995 actuals, FY 1996 estimates, and the FY 1997 President's budget request for each goal. In addition, the figures for funding of projects have been corrected, and new objectives (numbered 13, 14, and 15) have been added to the research goal. The budgets of the added objectives have been included in the tables. Some grants which received no FY 95 dollars have been included because they continued to be active in FY 95 with FY 94 dollars.

If you have any questions, please have your staff contact Ms. Phyllis Zucker, AHCPR AIDS Coordinator, at 301-594-2453.

Clifton R. Gaus, Sc.D.

Attachments

Prepared by: AHCPR/MJackson/emh/WP61/whrep 6/25/96ctrlA6338

cc: AHCPR Official
ES/OS
ES/AHCPR

SAMHSA	Reduce the rate of HIV transmission among high-risk substance abusers and their sexual partners Improve HIV/AIDS training of clinicians Improve the integration of substance treatment and primary medical care Reduce the number of new HIV infections	Objective 1: \$1,500,00 (With 1,500,000 from HRSA & \$1,400,000 from NIH) Objective 2: \$7,500,000 Objective 1: \$2,930,000 Objective 2: \$2,800,00 \$7,700,000 Objective 1: \$1,000,000 Objective 2: \$0 Objective 3: \$	Objective 1: \$1,500,00 (With 1,500,000 from HRSA & \$1,400,000 from NIH) Objective 2: \$7,500,000 Objective 1: \$2,800,000 Objective 2: \$0 Objective 1: \$3,000,000 Objective 2: \$5,000,000 Objective 3: \$	
AHCPR	To provide national estimates of the cost and use of HIV-related medical and non-medical services To provide national estimates of the cost and use of HIV-related prevention services To expedite the dissemination of data from research	~~\$6,744,430~~ 6,120,047 \$1,051,075 ✓ ~~\$318,835~~ 150,000	~~\$5,015,907~~ 4,420,393 ~~\$56,308~~ 77,473 ~~\$155,000~~ 0	4,186,582 0 0
IHS	Reduce the number of infections among Federally recognized American Indians and Alaska Natives	Objective 1: \$912,000 Objective 2: \$2,321,000	Objective 1: \$912,000 Objective 2: \$2,321,000	

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

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	4,150,657
FY 96:	\$4,000,000	3,462,114
FY 97:		3,131,582

Populations Served: HIV-infected individuals receiving treatment.

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

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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: 0

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: 0

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

***The National Strategy for HIV and AIDS – AHCPR Appendix
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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: 50,000

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.

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✓ ~~FY 95: \$394,557~~ 295,918
~~FY 96: \$39,455~~ 39,456
 FY 97: 0

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). \$0
~~FY 96: \$0~~
 FY 97: 0

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~~ 527,497
~~FY 96: \$420,000~~ 479,952
 FY 97: 505,000

***The National Strategy for HIV and AIDS – AHCPR Appendix
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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)~~ \$0
FY 96: \$0 \$0
FY 97: \$0

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: 5248,126 ✓
FY 96: ~~58,002~~ 8,003
FY 97: 0

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

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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)~~ \$0
FY 96: \$0 \$0
FY 97: \$0

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~~ 214,708
FY 97: 0

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
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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~~ 0

FY 97: 500,000

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

Constituency Involvement: N/A

Unmet Need: None.

***The National Strategy for HIV and AIDS -- AHCPR Appendix
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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~~ 56,453

FY 97: 0

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: ~~\$19,791~~ 21,020

FY 97: 0

Populations Served: Persons with HIV.

***The National Strategy for HIV and AIDS -- AHCPR Appendix
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Constituency Involvement: N/A

Unmet Need: None.

***The National Strategy for HIV and AIDS – AHCPR Appendix
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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~~ 0

FY 97: 0

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)~~ \$60,000

FY 96: ~~30,000 (to AIDS clearinghouse)~~ 0

FY 97: 0

***The National Strategy for HIV and AIDS – AHCPR Appendix
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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) 0

FY 96: \$0 ✓

FY 97: 0

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- 0

FY 97: 0

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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



DEPARTMENT OF HEALTH AND HUMAN SERVICES
WASHINGTON, D.C. 20201

✓ 2/12/97

EXECUTIVE SECRETARIAT

FACSIMILE

PLEASE NOTIFY OR HAND-CARRY THIS TRANSMISSION
TO THE FOLLOWING PERSON AS SOON AS POSSIBLE:

NAME:

Jane Sanville

ADDRESS:

MESSAGE:

FAX NUMBER:

632 - 1096

OFFICE NUMBER:

632 - 1090

FROM:

GLEN HARELSON
POLICY COORDINATOR

FAX NUMBER:

202 690-7203

OFFICE NUMBER:

202 690-7699

NUMBER OF PAGES (INCLUDING THIS ONE): 29

JUN-27-96 THU 15:57

FAX NO. 4431450

P. 04

Page 2 - Executive Secretariat, OS

drugs, however, SAMHSA recognizes that there is a 'hardcore' segment of the population that refuses treatment and will not practice prevention. The need to encourage prevention and treatment for this population is critical."

Following the fifth paragraph, "SAMHSA's new Knowledge Development Application (KDA) Program will address emerging issues in the fields of substance abuse and mental health, including a focus on HIV/AIDS. In addition, SAMHSA is a lead collaborator with other federal agencies to convene a forum of national leaders in the fields of substance abuse and HIV prevention to identify and explore steps for improving collaboration to prevent substance abuse and HIV infection in the United States.

Treatment for Sexually Transmitted Diseases and Tuberculosis, pg. 23

First paragraph, first sentence should read "Persons who are HIV positive...for the development of M. Tuberculosis (TB) disease."

SAMHSA Appendix, CARE AND SERVICES, pg. 1

(Changes made are in reference to the SAMHSA *HIV/AIDS Mental Health Services Demonstration Program*)

✓ Goal: To provide a range of high quality mental health services to people affected by or living with HIV/AIDS

✓ Objective: 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.

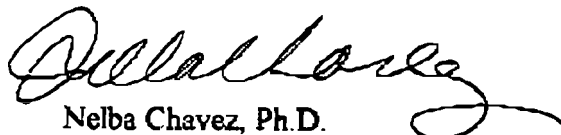
SAMHSA Appendix, PREVENTION, pg. 6

(Changes made are in reference to the SAMHSA *High Risk Youth Program*)

✓ Objective 1: Demonstrate the effectiveness of incorporating HIV/AIDS prevention curricula into ongoing substance prevention programs.

✓ FY 96: \$0

✓ (Changes made are in reference to the SAMHSA *Demonstration sites and community training Populations Served:* High risk neighborhoods, communities, including youth, families and community organizations.


Nelba Chavez, Ph.D.



Artists Organize To Help Clinton, Democrats In Fall Elections

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Harris Poll Shows Whitewater Hurting Clinton's Image

While President Clinton continues to hold a commanding lead over Republican Bob Dole in the polls, a Harris Poll finds that more people are having negative thoughts about the Clintons because of the Whitewater affair. Some 56 percent of the 1,005 polled July 9 to July 13 said they believe the president and Hillary Rodham Clinton did something illegal in the affair, up from 52 percent in June. Some 37 percent said they thought the Clintons did nothing wrong. Only 10 percent said they were ignorant of the scandal. "These trends are obviously not good news for the White House and the president's campaign team," said a Harris pollster. However, the poll shows that the Whitewater affair so far has had no impact on the president's re-election chances. But it does show that Americans harbor concerns about the president which could be exacerbated should the scandal continue to grow, said the pollster.

Both Sides Brace For Sleazy Campaign Sparked By Conventions

Democrats and Republicans alike are readying for "sleazy" attacks from the other party during the August national political conventions. Republicans, meeting next week in San Diego, are planning a frontal assault on the Democrats. And Democrats, meeting during the last week of August in Chicago, are planning a similar broadside against Republicans, especially House GOP members, led by House Speaker Newt Gingrich. The result will be an unusually high level of sleazy politics, several observers predicted. Marilyn Roberts, a professor of journalism and politics at the University of Florida, said both the campaigns will probably go negative in their bid for the White House. And she said the negative ads already planned by both sides are hurting the image of the presidency. But others note that a sleazy campaign really won't be anything new. Former President Bush used negative ads to his opponent Michael Dukakis in 1988. And as far back as 1828, Andrew Jackson's opponents used handbills and posters to accuse Jackson of adultery, ordering executions, stabbing a man in the back and murdering one of his own soldiers.

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Anti-Clinton Group Dogs President With Drug-Testing Station

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NEWS



BYTES

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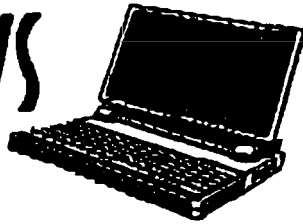
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Order of Appendices:

Appendix A: Prevention

Appendix B: Research

Appendix C: Care and Services

Appendix D: Civil Rights

Appendix E: International Activities

Appendix F: Translation of Research into Practice

OK with order of appendices?

PF -	☒ YES	☐ NO
JL -	☒ YES	☐ NO
RS -	☒ YES	☐ NO

8.5.96

Hello Gordon,

Attached are the appendices for the National AIDS Strategy that list the detailed budget figures. In the final report we plan to include the appendices and two summary budget tables -- one with funding by agency by year and one summarizing the budget levels for all the appendices. (The summary tables will be based on the detailed figures in the appendices.) We would also like to include Greg's history of AIDS funding table.

Attached are:

1. Appendix A: Prevention
Appendix B: Research
Appendix C: Care and Services
Appendix D: Civil Rights
Appendix E: International Activities
Appendix F: Translation of Research into Practice

Departments and agencies that support HIV-related activities in a policy area (i.e., prevention, research etc.) are listed in alphabetical order first by cabinet level department and then by agency.

2. Example of a summary table.

If you have any questions don't hesitate to call. Thanks.

Jane

632-1090

*** ERROR TX REPORT ***

TX FUNCTION WAS NOT COMPLETED

TX/RX NO	0553	
CONNECTION TEL		96907203
CONNECTION ID		
ST. TIME	07/31 12:51	
USAGE T	00'00	
PGS.	0	
RESULT	NG	
	0	#018

OFFICE OF NATIONAL AIDS POLICY EXECUTIVE OFFICE OF THE PRESIDENT

750 17th Street, N.W.
Washington, DC 20503

Phone: 202-632-1090

Fax: 202-632-1096

FACSIMILE COVER SHEET

TO: Glenn Harrelson

FAX NUMBER: 202-690-7203

FROM: Jane Sanville

DATE: 7.31.96

PAGES INCLUDING COVER SHEET: 3

COMMENTS:

Glenn Harrelson is the director of the

**OFFICE OF NATIONAL AIDS POLICY
EXECUTIVE OFFICE OF THE PRESIDENT**

750 17th Street, N.W.
Washington, DC 20503

Phone: 202-632-1090
Fax: 202-632-1096

FACSIMILE COVER SHEET

TO: Glenn Harrelson

FAX NUMBER: 202-690-7203

FROM: Jane Sanville

DATE: 7.31.96

PAGES INCLUDING COVER SHEET: 3

COMMENTS:

Glenn- Here is the IHS appendix as it
will go into the AIDS Strategy Appendix.

If you have any changes please
let me know by COB today. If I don't
hear ^{from you}, I'll assume this is ok.

Thanks for your help - Jane

FY 95 323,000
94 "
97

PREVENTION

Agency: Department of Health and Human Services, Indian Health Service

Goal: To 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: Budget figure unavailable. 1,800,000

Populations Served: Federally recognized American Indians and Alaska Natives.

Constituency Involvement: Local and National Indian Health Advisory Boards.

Unmet Need: Increased staff and resources would permit expansion of prevention activities.

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: *HIV health educ r risk reduction message dissem*
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: Budget figure unavailable.

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

Constituency Involvement: Local and National Indian Health Advisory Boards.

Unmet Need: Increased staff and resources would permit expansion

FY 95 912,000
96 912,000
97 1,800,000

of prevention activities.

CARE AND SERVICES

Agency: Department of Health and Human Services, Indian Health Service

Goal: To provide health care for federally recognized American Indians and Alaska Natives who are HIV positive.

Objective: Provide HIV-related health care within Indian Health Service-supported care systems for American Indians and Alaska Natives.

Action Steps: In coordination with area AIDS Coordinators, provide HIV-related health care.

Descriptions: HIV-related health care and services.

FY 95: Budget figure unavailable.

FY 96: Budget figure unavailable.

FY 97: Budget figure unavailable.

Part overall IHS funding.

Populations Served: Federally recognized American Indians and Alaska Natives.

Constituency Involvement: Local and National Indian Health Advisory Boards.

Unmet Need: Increased staff and resources would permit expansion of HIV-related health care activities.

07/24/96 10:40

Wertheimer, Wendy

From: Wertheimer, Wendy
To: Ursula Sanville
Cc: Jeffrey Levi; Whitescarver, Jack; wepaul
Subject: FW: NIH Goals for National Strategy
Date: Wednesday, July 24, 1996 3:50PM

Jane -- We have redrafted the goals.

Goal: To conduct and support natural history and epidemiological research to improve the understanding of the risk factors and mechanisms of HIV transmission and disease progression and to develop prevention strategies to reduce or prevent HIV transmission.

Goal: To conduct and support research to improve the understanding of HIV and the pathogenic mechanisms of HIV disease.

Goal: To conduct and support preclinical and clinical research to develop, test, and optimize treatments for HIV infection, HIV-associated conditions, and for the prevention of HIV transmission.

Goal: To conduct and support basic, preclinical, and clinical research to develop a safe and effective preventive HIV vaccine.

Goal: To conduct and support behavioral and social science research to further understanding of the determinants and processes that influence behaviors associated with HIV transmission and to develop and improve HIV prevention interventions strategies.

Goal: To provide appropriate training and infrastructure for the conduct of HIV-related biomedical and behavioral research domestically and internationally.

Goal: To support effective dissemination, communication and utilization of HIV-related research information to researchers, health care providers, HIV-related service providers, HIV-infected individuals and their advocates, and all constituencies of the NIH.

Handwritten note: *Handwritten "JN" circled, with "individual by area files" written next to it.*

Handwritten note: *Jane.*

Handwritten note: *I gave Jeff a copy also.*

Handwritten note: *DCM*

E X E C U T I V E O F F I C E O F T H E P R E S I D E N T

31-Jul-1996 12:53pm

TO: Jeffrey Levi

FROM: Ursula Sanville
 AIDS Policy Council

SUBJECT: Strategy things

Jeff --

If you want to take a look at the intro it's under n:\jeff1.g96. I took your shorter version and made changes based on my read and the disussion that took place here while you were on "vacation". Let me know if you have any changes/comments.

I have a meeting at noon tomorrow with the printer. Plan to go over:

1. Layout for Appendices. The version I'm planning to give them will inlcude your changes and final agency changes. OK? *Yes let them know. Current Federal Activities*

I'd also like you to look at the prototype today to make sure you're comfortable with it.

2. Cover design. The title we want to go with is "The National AIDS Strategy" -- correct? Do we want the Presidential seal, and/or the White House on the cover? *Not yet.*

3. Executive Summary. Last we talked we were going to do a stand alone ES. Is this still what you want to do? - *Maybe just text. & appendices.*

Let me know if there is anything else you would like to me to go over at this meeting.

Jane



U.S. Department of Justice

Office of Policy Development

Washington, D.C. 20530

July 23, 1996

MEMORANDUM

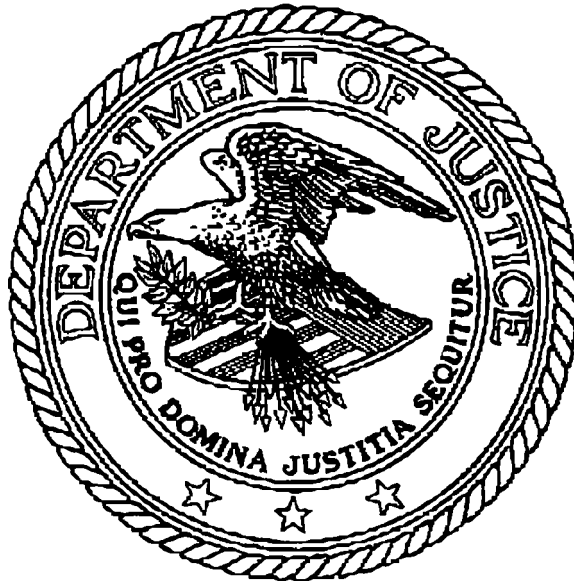
TO: Jane Sanville
Office of National AIDS Policy

FROM: Lisalyn R. Jacobs
Counsel

LRJ

SUBJECT: Final Edits to the Appendix of the National Plan

Hopefully, we can resolve the "parallel structure" concern in the following way. In the Civil Rights section, all three fiscal years should say: "Information line \$350,000, complaint investigation and other enforcement activities are part of the overall operating budget." An additional sentence in the FY '97 line should read: "The President's 1997 budget requests a 3.9% increase for ADA enforcement."



Office of Policy Development
United States Department of Justice
10th and Constitution Ave. NW
Washington, D. C. 20530

TO: Jane Sanville
Office of National AIDS Policy

FAX: ()632-1096

FROM: Lisalyn R. Jacobs
Counsel

VOICE: (202) 514-3824
FAX: (202) 514-5715

Total Pages (excluding this cover): 1

Additional Message: In case I'm not able to catch up with you, my proposed "fix" for the appendix is attached.

LRJ

WASHFAX RECEIPT
DEPARTMENT OF STATE**B**

'96 JUL 22 PM 10 06

96 JUL 22 P9:43
S/S #

MESSAGE NO. 039204 CLASSIFICATION (U) No. Pages 2
FROM: W. Burns S/S 647-1512
(Officer name) (Office symbol) (Extension) (Room number)
MESSAGE DESCRIPTION As requested

TO: (Agency)	DELIVER TO:	Extension	Room No.
<u>WH</u>	<u>Jane Sanville</u>	<u>632-1090</u>	

FOR: CLEARANCE ☐ INFORMATION ☐ PER REQUEST ☐ COMMENT ☐REMARKS: _____

S/S Officer: _____



United States Department of State

Washington, D.C. 20520

UNCLASSIFIED

MEMORANDUM FOR PATRICIA S. FLEMING
WHITE HOUSE OFFICE OF NATIONAL AIDS POLICY

Subject: Clearance Request for the National Strategy on
HIV and AIDS

The Department of State clears on the attached draft
National Strategy for HIV and AIDS.

A handwritten signature in cursive script, appearing to read "Will J. Burns".

William J. Burns
Executive Secretary

Attachments:

1. Concurrence sheet.
2. Incoming memorandum.

UNCLASSIFIED

1

THE OFFICE OF NATIONAL AIDS POLICY
CONCURRENCE SHEET

RETURN BY MONDAY, JULY 22, 1996

Please check the applicable box and sign in space provided.

THE NATIONAL STRATEGY FOR HIV AND AIDS

- ☒ a. I approve the National Strategy for HIV and AIDS
- ☐ b. I approve the National Strategy for HIV and AIDS with minor editing (attach comments)

	OES	7/22/96	202-647-1554
Signature	Department	Date	Telephone #

Return by FAX to:
Jane Sanville
202-632-1096

FAILURE TO RESPOND BY JULY 22, 1996 PRESUMES CONCURRENCE

July 18, 1996
CHECK-IN

1. Meetings and conference calls today

9:30 am: DPC conference call

Other meetings/calls:

2. Other Stuff

- Who's out today ...
- Who's out next week ...
- Work for next regional briefing ...

3. Round Robin

HOPWA - 97

\$196 million

AMPAD
EFFICIENCY® 23-023 **CARBONLESS**

 **AMPAD**
EFFICIENCY®

23-023 CARBONLESS

Richard → @lunch.
Sush = State Department.
Delivered everything OK.
Messages -
② Good news - 202 to 22 0059
Sandy Mancini -
when text policy
- handled it. Went to office of
international affairs.
Fax from her arrived.

Brill memo —
Executive

To the Executive — Secretary.

Secretary Office

~~21st~~ + 2201 C Street

Come in C Street entrance
- Reception desk.
- will give instructions

▶ photo ID
D.O.B. + SSN

Room 4330

Jonathan Davis

847-4542

Delivering
to two
places.

Call Jonathan
before leaving —
to clear.
After 10:00

Jeff Draft for State. Comments please. Jane

July 16, 1996

MEMORANDUM TO THE SECRETARY OF STATE

FROM: PATRICIA S. FLEMING

SUBJECT: Clearance request for the National Strategy on HIV and AIDS

I am requesting your clearance of the National Strategy for HIV and AIDS. I need your final clearance by July 22, 1996.

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

As a result of our meetings last year, each member of the Interdepartmental Task Force on HIV/AIDS (IDTF) developed ~~individual department and agency~~ plans for HIV/AIDS, linking goals and objectives to budget levels and identifying areas of unmet need. This past February, IDTF members reviewed the draft and provided comment. The document was revised based on these comments and circulated again for final review.

The portions of the document relevant to the State Department have been developed in collaboration with Anne K. Solomon, Deputy Assistant Secretary for Science, Technology, and Health. The State Department's sections were based on the Department's United States International Strategy on HIV/AIDS (July 1995) and information provided by Ms. Solomon's staff.

Attached is the final language for the Department of State's appendix and the main text of the National Strategy. Ms. Solomon has seen this document and had no further comments, as communicated in her letter of July 3, 1996.

Your timely review and clearance of this document is appreciated. Please send your clearance using the attached form to Jane Sanville at fax 202-632-1906, phone 202-632-1090.

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

**THE OFFICE OF NATIONAL AIDS POLICY
CONCURRENCE SHEET**

RETURN BY MONDAY, JULY 22, 1996

Please check the applicable box and sign in space provided.

THE NATIONAL STRATEGY FOR HIV AND AIDS

- ____ a. I approve the National Strategy for HIV and AIDS
- ____ b. I approve the National Strategy for HIV and AIDS with minor editing (attach
 comments)

Signature Department Date Telephone #

Return by FAX to:
Jane Sanville
202-632-1096

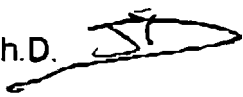
FAILURE TO RESPOND BY JULY 22, 1996 PRESUMES CONCURRENCE



**Emerging Infectious Diseases Program
Bureau of Oceans and International Environmental and Scientific Affairs
United States Department of State
Washington, D.C. 20520**

FAX COVER SHEET

TO: Jane Sanville
Office of National AIDS Policy
Executive Office of the President
Tel: 202-632-1090
Fax: 202-632-1096

FROM: Jonathan Davis, Ph.D. 
STATE/OES/S
Tel: 202-647-4542
Fax: 202-736-7336
Email: jdavis@state.gov

DATE: 16 July 1996

RE: National Strategy on HIV/AIDS

As per our discussions, enclosed please find an example of a clearance request that recently came through channels. I hope that you find this useful.

Thank you very much.

THE WHITE HOUSE

WASHINGTON

May 1, 1996

MEMORANDUM TO MEMBERS OF
THE NATIONAL SCIENCE AND TECHNOLOGY COUNCIL

FROM: JOHN H. GIBBONS 

SUBJECT: Clearance request of the Presidential Decision Directive on Emerging Infectious Diseases

I am requesting your clearance of the attached Presidential Decision Directive (PDD) on Emerging Infectious Diseases (EID). I would appreciate your final clearance by Wednesday, May 15, 1996.

The PDD would establish national policy and implementing actions to address the threat of emerging infectious diseases by improving domestic and international surveillance, prevention, and response measures. It calls for coordination of basic research, training, public health programs, foreign assistance, and security measures. The PDD is based on the recommendations of the NSTC report, Infectious Diseases: A Global Health Threat, and the agencies' responses to the OSTP/NSC tasker on EID's. The objectives of the PDD include the following:

- Strengthen domestic EID surveillance and response at Federal, State and local levels.
- Work with other nations and international organizations like WHO to establish a global surveillance and response system.
- Strengthen biomedical and biobehavioral research on EID's.
- Ensure availability of drugs, vaccines, and diagnostics.
- Expand missions and mandates of relevant agencies, such as CDC and DoD, to enable them to participate in an international EID surveillance network.

The PDD has been reviewed by the NSTC Committee on International Science, Engineering, and Technology (CISST) and incorporates CISST comments. The PDD is being reviewed by OMB as part of the NSTC clearance process.

Your timely review and clearance of this document is appreciated. Please send your clearance using the attached form by facsimile to Angela Phillips Diaz, Executive Secretary of the NSTC (fax: 202-456-6026, phone: 202-456-6100) by close of business Wednesday, May 15, 1996. If we do not receive clearance by this date, your concurrence will be assumed.

Attachments

NATIONAL SCIENCE AND TECHNOLOGY COUNCIL
CONCURRENCE SHEET

RETURN BY WEDNESDAY, MAY 15, 1996

Please check the applicable box and sign in space provided.

PRESIDENTIAL DECISION DIRECTIVE ON EMERGING INFECTIOUS
DISEASES

- _____ a. I approve the Presidential Decision Directive.
- _____ b. I approve the Presidential Decision Directive with minor editing
(attach comments).
- _____ c. I would like to have further discussion with the CISET Principals before
approving the Presidential Decision Directive.

Signature

Agency

Date

Telephone #

Return by FAX to:
Angela Phillips Diaz
(202) 456-6026

FAILURE TO RESPOND BY MAY 15, 1996 PRESUMES CONCURRENCE.

Office of
National AIDS Policy

Correspondence Routing Slip

Tracking Number: G3156

Date Rcvd: 7-11-96

From: United States Department of State
ANNE K. Solomon

Staff Action:

Reviewed By Jeff: _____ Reviewed By: Patsy _____

Assigned To: _____

RCVD: _____ DONE: _____

Recommendations/Instructions:

To Support Staff: _____

Date of Response: _____



United States Department of State

*Bureau of Oceans and International
Environmental and Scientific Affairs*

Washington, D.C. 20520

July 3, 1996

Ms. Patricia S. Fleming
Director, Office of National AIDS Policy
Executive Office of the President
750 17th Street, N.W.
Washington, D.C. 20503

Dear Patsy:

We have no further comments on the language for the Department of State appendix as part of the National Strategy for HIV and AIDS. Your office has done an exemplary job in developing the overall Strategy and linking goals and objectives to budget levels of the individual Departments and agencies.

As I mentioned to you in my letter of 01 March 1996, the OES Bureau continues to serve a coordinating role in implementing the U.S. International Strategy on HIV/AIDS. Since that letter we have made progress to provide the personnel necessary to move these actions forward. In response to the Secretary of State's new initiatives, OES has created a new office for emerging infectious diseases, including HIV/AIDS. The Director for the new office is Nancy Carter-Foster, and she will be my point of contact for these issues. Nancy has many years experience at State as a policy analyst and negotiator for health and population issues. She can be reached at 647-2435 (phone) or 736-7336 (fax).

I hope that I have provided you with the information you need. If you have any questions or require additional information, please do not hesitate to contact me. I look forward to our next meeting.

With best regards.

Sincerely yours,

A handwritten signature in cursive script, reading "Anne K. Solomon".

Anne K. Solomon
Deputy Assistant Secretary
Science, Technology, and Health

7.16.96

By Kennedy
By Area
By Goal

National Strategy -- what's left

Executive Summary

Within full document plus stand-alone?

PF message, intro sections,
budget tables.

Dept/Agency comments yet to be received --

HHS - Title - budget #'s

ONDCP - Title

Education - Title

Treasury

Energy - Called.

State (concurrence at Secretary level)

NSC

Jeff Blaylock, OMB(VA)

Comments to be incorporated --

HHS packet

NIH comments

NIH appendix

goals -

unmet need -

constituency involvement -

DOJ prisoner prevention language -

MC's project with review from ?? -

email to Jeremy -
which need help.
HHS/ until PF spoke Kern.

Updating budget tables

Budget tables to OMB for review ->

HIV is one of those issues,
so cross-cutting (PF's letter...)

Media plan --

RS proposal to bring in NIH, HHS, etc.

Rollouts -- timing, which groups (had discussed hill

groups, specialty press) if Pres. event -> after. If not, before.

Rollouts -- do we need a conference call with the PAC

MC's issue

FedEx night before.

Copy to JS

Implementation plan

crosswalk with PAC and National Commission Recommendations

Title of plan

Printers

layout of cover page

number of copies/time to copy

500 full copies

500 Executive summaries

• photos of charts tables

Acronym list.



August 8th -

August 7th - pre brief

5th - printing done ~~at~~

31st - to printer (Wednesday).

23rd - FedEx to H in hurry @ latest.

25th - final ONAP Review. - PF, RS, LR, SD, MC

18th - outstanding comments →

7.16.96

National Strategy -- what's left

Executive Summary

Within full document plus stand-alone?

Dept/Agency comments yet to be received --

HHS ✓
ONDCP ✓
Education
Treasury
Energy
State (concurrence at Secretary level)
NSC }

*1 Glen budget
figures!*

Called 7.16

Comments to be incorporated --

HHS packet ✓
NIH comments ✓
NIH appendix
 goals
 unmet need }
 constituency involvement
DOJ prisoner prevention language ✓
MC's project with review from ?? ✓

Updating budget tables

Budget tables to OMB for review

Media plan --

RS proposal to bring in NIH, HHS, etc.
Rollouts -- timing, which groups (had discussed hill,
 groups, specialty press)
Rollouts -- do we need a conference call with the PAC

Copy to JS

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Printers

layout of cover page
number of copies/time to copy
 500 full copies
 500 Executive summaries

*C/wor/... NP/ADMIN
STATE. 596*

*NP
C. WNK/WR/MSI/ADMIN/DISIMEMO/ENERGY. E96
/CHARTS/ " "*

**OFFICE OF NATIONAL AIDS POLICY
EXECUTIVE OFFICE OF THE PRESIDENT**

750 17th Street, N.W.
Washington, DC 20503

Phone: 202-632-1090
Fax: 202-632-1096

FACSIMILE COVER SHEET

TO: Barbara Roberts

FAX NUMBER: 395-6744

FROM: Jane Samille

DATE: 7.18.96

PAGES INCLUDING COVER SHEET: 8

COMMENTS:

Barbara - Here's the Sunset A appendix with the text changes. Any questions let me know.

Jane

Jane:

Richa McMahon, ONDCP

395-6706

Has question about when they will get to see the whole document for clearance.

Jeff - please
look @ the
ONDCP part.

E X E C U T I V E O F F I C E O F T H E P R E S I D E N T

19-Jul-1996 07:30pm

TO: Jeremy D. Benami
FROM: Ursula Sanville
 AIDS Policy Council
CC: Jeffrey Levi
SUBJECT: Follow-up on National AIDS Strategy

 Jeremy --

I'm following up on where we stand with the outstanding clearances and/or text submissions.

- DHHS: Jeff has spoken to Kevin Thurm and he promised to push for resolution in the Department on Monday.
- State: The concurrence is due Monday. Did not receive anything early.
- NSC: Are we ok there?

- Education: The information they sent was incomplete and they could not be reached to discuss. We need help with this -- the contact person is William Modzelski at 260-3954. The person who has been working on the document (Modzelski was out this week) is Ms. Gillespie at the same number.

- ONDCP: A significant problem.

1. They promised text on the ONDCP mission and activities by COB today and we have received nothing. They also refused to provide information for an appendix as "ONDCP is not an appendix to anyone else's report."
2. They want to review all the budget figures so they can assess whether the AIDS activities sponsored by other departments and agencies are in line with the ONDCP goals.
3. They are balking on giving concurrence ~~unless~~ without seeing the copy that is going to the printers (they have a copy with the final "substance" now), and, the General is comfortable that the AIDS report and cited activities are in line with ONDCP's mission, etc.

^{OK}
They ~~were told~~ about the 7.22 deadline for going to the printers. We need assistance in getting their text, and reinforcing that the budget review is by OMB, not ONDCP.

Thanks for your help, any questions let me know.

SUGGESTED PARAGRAPH RE GRANDMOTHERS FOR PATSY FLEMING LETTER IN THE NATIONAL STRATEGY - MC Smothermon

Jane - Below are two paragraphs. The first could be a stand alone if there is not room for the second, although I would like to see both included.

I would place this information on page 4 between the paragraph starting at the end of column one ("There is also fear.....") and the one beginning "Despite the many difficulties....."

*CROSS-cutting - example -
HHS ~~and~~ agencies. ACF + SSA +*

AIDS orphans are a hidden epidemic within the larger context of HIV/AIDS. Some are HIV-infected, all are HIV-affected. Many of these children already have or will become wards of the state, shuffled between foster and group homes, often separated from their siblings. They will fall through the cracks of a system which is not prepared to acknowledge or care for them.

We are seeing an increasing number of grandparents becoming parents to their grandchildren, even as they deal with the illness and death of their own child. There is a need to be sure parental rights are maintained as long as possible, but also to facilitate the orderly and legal transfer of custody upon incapacitation or death of the parent(s).



9612366

United States Department of State

Washington, D.C. 20520

July 22, 1996

UNCLASSIFIEDMEMORANDUM FOR PATRICIA S. FLEMING
WHITE HOUSE OFFICE OF NATIONAL AIDS POLICYSubject: Clearance Request for the National Strategy on
HIV and AIDSThe Department of State clears on the attached draft
National Strategy for HIV and AIDS.William J. Burns
Executive Secretary

Attachments:

1. Concurrence sheet.
2. Incoming memorandum.

DATE SENT:	7/22/96	CLASSIFIED MATERIAL	v 3234787	
		Copy For Addressee		
FROM:	Chief	SS/RMD:jm	7512	NS
	(Name)	(Office Symbol)	(Room No.)	(Bldg.)
TO:	Lance Alworth (National AIDS Policy)			
	(Name)	(Office Symbol)	(Room No.)	(Bldg.)
PART V	Suite 600 750 17th St., N.W.			
DATE RECEIVED:				
IDENTIFICATION	9612366			

Optional Form 112
Rev. 8/79
State AID USICATHIS PART MAY BE USED FOR DISTRIBUTION AND/OR
DESTRUCTION - 5 FAM 975.B AND 960.4
RETAINED FOR 3 YEARSUNCLASSIFIED

Clinton Presidential Records Digital Records Marker

This is not a presidential record. This is used as an administrative marker by the William J. Clinton Presidential Library Staff.

This marker identifies the place of a tabbed divider. Given our digitization capabilities, we are sometimes unable to adequately scan such dividers. The title from the original document is indicated below.

1

Divider Title: _____

**THE OFFICE OF NATIONAL AIDS POLICY
CONCURRENCE SHEET**

RETURN BY MONDAY, JULY 22, 1996

Please check the applicable box and sign in space provided.

THE NATIONAL STRATEGY FOR HIV AND AIDS

- ☒ a. I approve the National Strategy for HIV and AIDS
- ☐ b. I approve the National Strategy for HIV and AIDS with minor editing (attach comments)

	OES	7/22/96	202-647-1554
Signature	Department	Date	Telephone #

Return by FAX to:
Jane Sanville
202-632-1096

FAILURE TO RESPOND BY JULY 22, 1996 PRESUMES CONCURRENCE

Clinton Presidential Records Digital Records Marker

This is not a presidential record. This is used as an administrative marker by the William J. Clinton Presidential Library Staff.

This marker identifies the place of a tabbed divider. Given our digitization capabilities, we are sometimes unable to adequately scan such dividers. The title from the original document is indicated below.

2

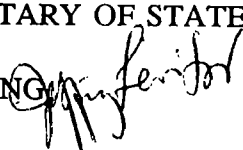
Divider Title: _____

ACTION OFFICE: OES
COPIES TO:
G
S/S
S/S-IA
M/DGP
RF
(HEW)

THE WHITE HOUSE
WASHINGTON
July 16, 1996

9612366

MEMORANDUM TO THE SECRETARY OF STATE

FROM: PATRICIA S. FLEMING 
SUBJECT: Clearance request for the National Strategy on HIV and AIDS

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The portions of the document relevant to the State Department have been developed in collaboration with Anne K. Solomon, Deputy Assistant Secretary for Science, Technology, and Health. The State Department's sections were based on the Department's United States International Strategy on HIV/AIDS (July 1995) and information provided by Ms. Solomon's staff.

Attached is the final language for the Department of State's appendix and the main text of the National Strategy. Ms. Solomon has seen this document and had no further comments, as communicated in her letter of July 3, 1996.

Your timely review and clearance of this document is appreciated. Please send your clearance using the attached form to Jane Sanville at fax 202-632-1906, phone 202-632-1090.

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

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***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.

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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.

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Executive Summary

== Place Holder ==

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.¹ 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

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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 1992.² 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 disease³, \$25,000 to 84,000 for Cancer⁴, and \$119,000 for HIV/AIDS⁵. 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)⁶, 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 Syndrome⁷, the "Coolfont"⁸ and "Charlottesville"⁹ reports, and the PHS Strategic Plan to Combat HIV and AIDS in

the United States¹⁰. Recommendations have also been issued by a number of groups, including the National Commission on AIDS¹¹ 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 a 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.¹² 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

strategies¹³, the CDC has initiated efforts to evaluate current data collection efforts and implement necessary changes, and this work should continue.

Prevention Research¹⁴

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.¹⁵ 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.¹⁶ [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.¹⁷ Studies have shown that community-based HIV risk reduction programs that are gender relevant and culturally sensitive can be effective.¹⁸ 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.¹⁹

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.^{20, 21} 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.²² 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.

Prisoners. Populations in prisons are at high risk for both substance abuse and HIV disease. Moreover, there is often a high prevalence of both HIV and substance abuse behaviors in people entering prison.

Given that the incarcerated population is often at increased risk for HIV infection, offering educational programs during incarceration provides a unique opportunity

to reach these persons. Studies have found that programs using peer counselors have been effective in delivering HIV treatment and prevention messages. Research has also shown that individuals who are well informed about HIV and substance abuse issues do modify their risk-taking behaviors. It is important the Federal government build upon the knowledge and opportunity that currently exists and further improve HIV prevention efforts for incarcerated persons.

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 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 expedited review and accelerated approval programs, 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 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 STDs²³. 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. Models of collaboration have been developed to improve our understanding of disease and health in adolescents; several PHS agencies have cooperatively established the Adolescent Medicine HIV/AIDS Research Network. 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 program²⁴, 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 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.²⁵

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.²⁶ 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).²⁷ 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.²⁸ Other research indicates that a disturbing number of clinicians do not use universal precautions in the course of routine patient care.²⁹

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

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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

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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.

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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.

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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.

20. Heiner Grosskurth, Frankc Mosha, James Todd, Extra Mwijarubi, Arnould Clokke, Kesheni Senkoro, Philippe Mayaud, John Chagalucha, Angus Nicoll, Gina ka-Gina, James Newell, Kokuugonza Mugeye, David Mabey, Richard Hayes. Impact of Improved Treatment of Sexually Transmitted Diseases on HIV Infection in Rural Tanzania: Randomized Controlled Trial. The Lancet, Vol. 346, August 26, 1995.

21. Maria Wawer, Science. 9.08.95, vol. 269, No. 5229

22. Personal communication from CDC Division TB Elimination.

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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

Department of State Appendix

INTERNATIONAL ACTIVITIES

Agency: U.S. Department of State

Goal: Promote more active involvement on HIV/AIDS issues by foreign governments.

Objective: Persuade foreign governments to increase national and global activities to stem the spread of HIV/AIDS and to mitigate its impact.

Action Steps: Overseas posts will communicate the major objectives of the U.S. International Strategy on HIV/AIDS to host country officials.

Description: Initiative to increase commitment of foreign leaders.

FY 95: Not applicable.

FY 96: Not applicable.

FY 97: Not applicable.

Population Served: Nations affected by HIV/AIDS, PWAs globally and populations threatened by HIV/AIDS.

Constituency Involved: U.S. State Department, foreign governments, NGOs and business groups.

Unmet Needs: Budget and personnel constraints limit the Department's ability to coordinate actions identified in the International Strategy on HIV/AIDS document.

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Agency: U.S. Department of State

Goal: Enhance U.S. participation on HIV/AIDS issues internationally.

Objective 1: Address HIV/AIDS in all appropriate international fora.

Action Steps: Ensure that the U.S. International Strategy is promoted at relevant international meetings of the U.N. and other bodies. Convene interagency meetings to discuss the international calendar and to develop cohesive approaches to AIDS issues.

Description: Implementation of the U.S. International Strategy on HIV/AIDS.

FY 95: Not applicable.

FY 96: Not applicable.

FY 97: Not applicable.

Population Served: Nations affected by HIV/AIDS, PWAs globally and populations threatened by HIV/AIDS.

Constituency Involved: U.S. State Department and other federal agencies.

Unmet Needs: Budget and personnel constraints limit the Department's ability to coordinate actions identified in the International Strategy on HIV/AIDS document.

Objective 2: Assist U.S. agencies in improving responsiveness to a range of HIV/AIDS-related issues.

Action Steps: Address the issue of the spread of AIDS in international peacekeeping and humanitarian missions. Explore possibilities for closer collaboration with MDBs to stem the spread of AIDS.

Description: Improving U.S. responsiveness.

FY 95: Not applicable.

FY 96: Not applicable.

FY 97: Not applicable.

Population Served: Nations affected by HIV/AIDS, PWAs around the world and populations threatened by HIV/AIDS.

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Constituency Involved: U.S. State Department and MDBs.

Unmet Needs: Budget and personnel constraints limit the Department's ability to coordinate actions identified in the International Strategy on HIV/AIDS document.

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Agency: U.S. Department of State

Goal: Enhance awareness of implications of HIV/AIDS worldwide.

Objective 1: Heighten awareness of Congress as to implications of global HIV/AIDS on U.S. foreign policy.

Action Steps: Communicate to Congress the implications of global HIV/AIDS for foreign policy initiatives. Support biomedical research and international prevention efforts as means of reducing potential impact.

Description: Communicate implications of U.S. International Strategy on HIV/AIDS to Congress.

FY 95: Not applicable.

FY 96: Not applicable.

FY 97: Not applicable.

Population Served: Nations affected by HIV/AIDS, PWAs globally, populations threatened by HIV/AIDS and the U.S. Congress.

Constituency Involved: U.S. State Department.

Unmet Needs: Budget and personnel constraints limit the Department's ability to coordinate actions identified in the International Strategy on HIV/AIDS document.

Objective 2: Heighten awareness within the U.S. foreign service community and other U.S. agencies of the foreign policy implications of global HIV/AIDS.

Action Steps: Distribute International Strategy on HIV/AIDS to embassy personnel;

Hold workshop on the global implications of HIV/AIDS;

Use training sessions and individual briefings of foreign service personnel to discuss HIV/AIDS as a foreign policy concern;

Work with U.S.-based international businesses to gain a better understanding of the economic impact of global HIV/AIDS on U.S. business; and

Continue to include HIV/AIDS-related discrimination and human rights abuses in regular

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embassy reporting.

Description: Inform and educate U.S. foreign service personnel.

FY 95: Not applicable.

FY 96: Not applicable.

FY 97: Not applicable.

Population Served: Nations affected by HIV/AIDS, PWAs globally, populations threatened by HIV/AIDS and State Department foreign service personnel.

Constituency Involved: U.S. State Department.

Unmet Needs: Budget and personnel constraints limit the Department's ability to coordinate actions identified in the International Strategy on HIV/AIDS document.

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Agency: U.S. Department of State

Goal: Support U.S. technical agencies.

Objective: Support U.S. technical agencies in fulfilling the international HIV/AIDS objectives as appropriate to their individual agency mandates.

Action Steps: Assist USG agencies in strengthening or establishing international research and training collaborations and in gaining approval for HIV/AIDS vaccine trials and other research efforts.

Description: Support for international research.

FY 95: Not applicable.

FY 96: Not applicable.

FY 97: Not applicable.

Population Served: Nations affected by HIV/AIDS, PWAs globally, populations threatened by HIV/AIDS, researchers and USG agencies.

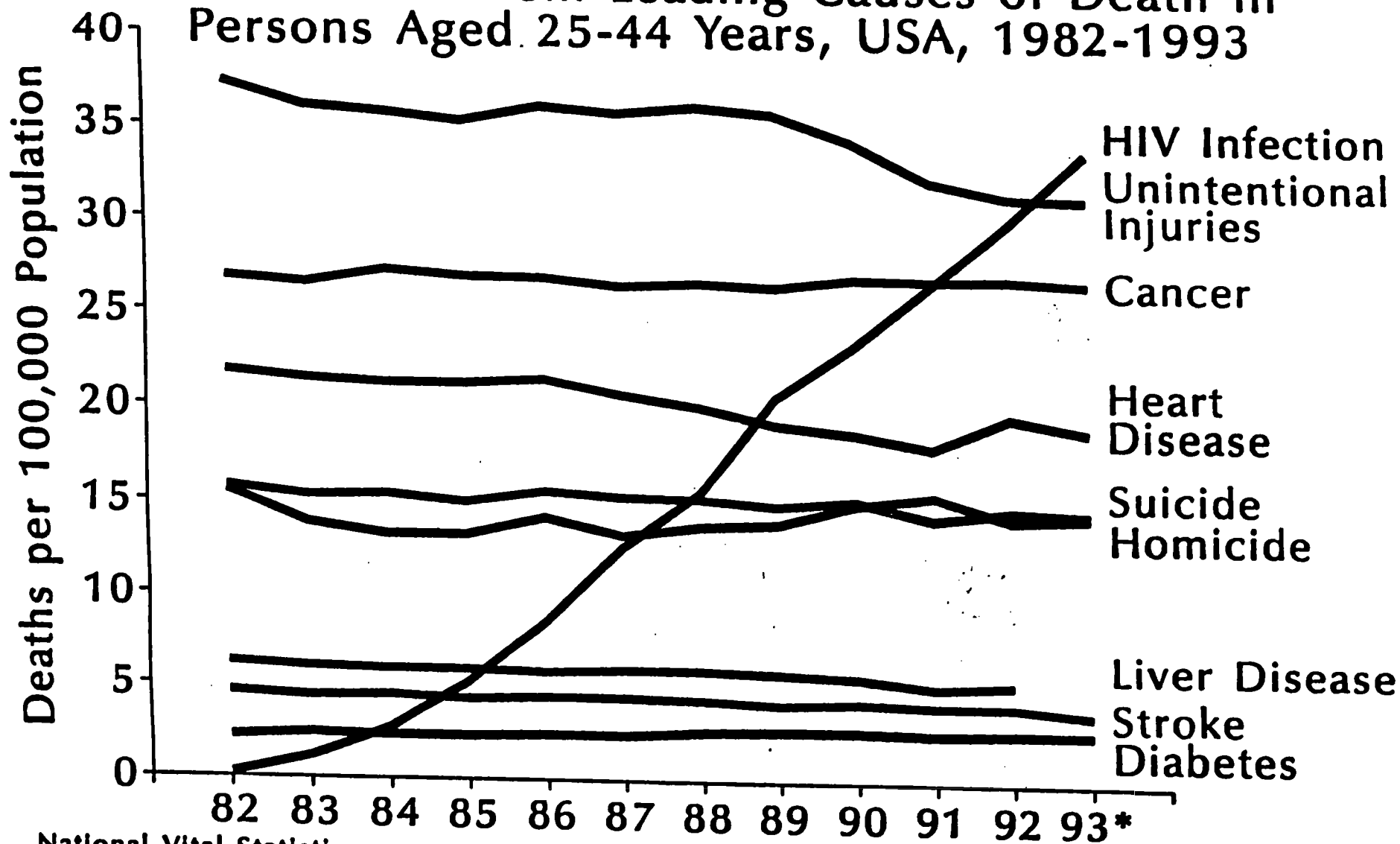
Constituency Involved: U.S. State Department, USG agencies and researchers.

Unmet Needs: Budget and personnel constraints limit the Department's ability to coordinate actions identified in the International Strategy on HIV/AIDS document.

***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

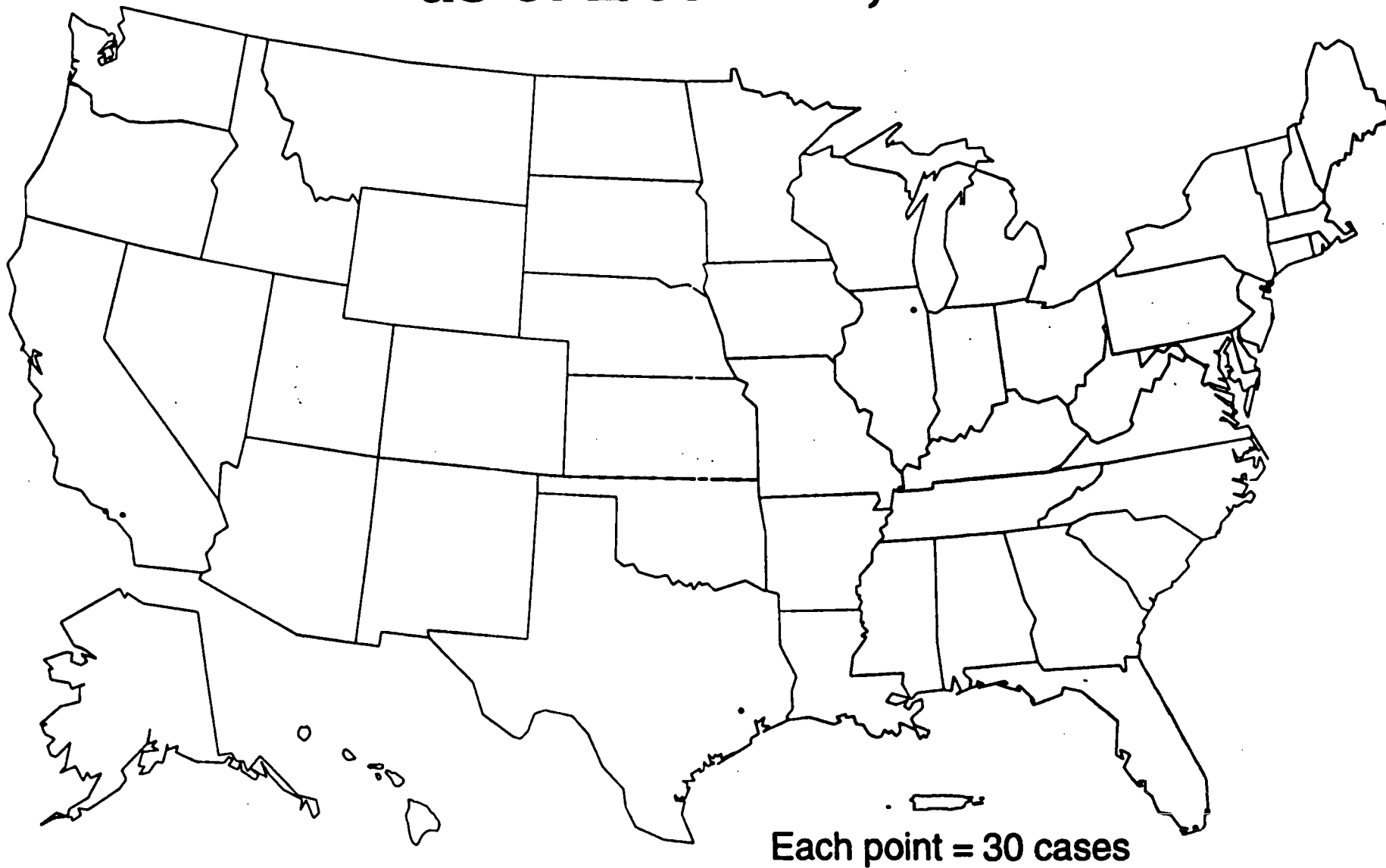
*Provisional data

CDC

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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

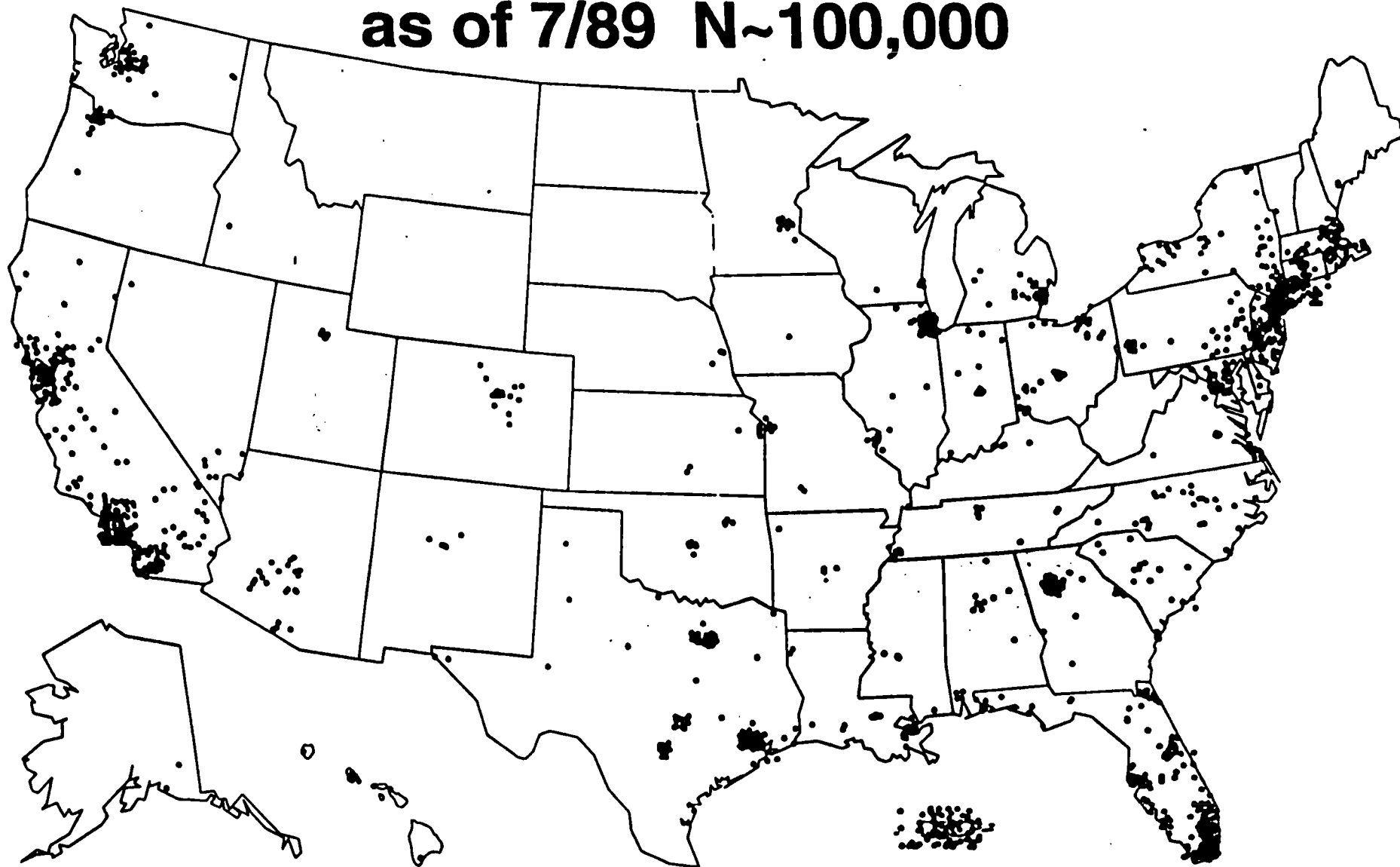


Cumulative U. S. AIDS Cases as of 5/85 N~10,000



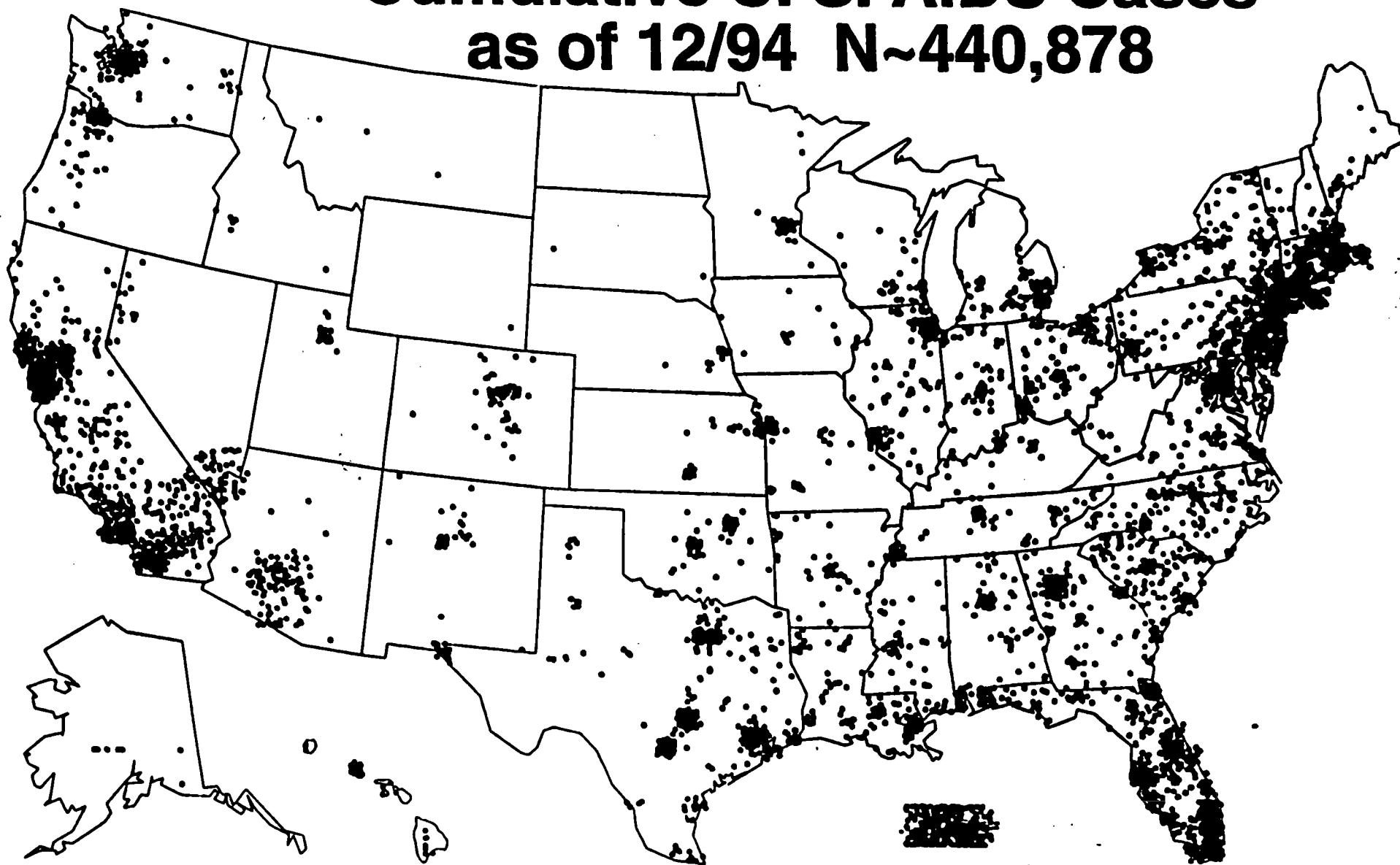
Each point = 30 cases

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



Each point = 30 cases

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



Each point = 30 cases

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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

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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

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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