

# FOIA MARKER

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| <b>Collection/Record Group:</b>   | Clinton Presidential Records |
| <b>Subgroup/Office of Origin:</b> | National AIDS Policy Office  |
| <b>Series/Staff Member:</b>       | Patsy Fleming                |
| <b>Subseries:</b>                 | National AIDS Strategy       |

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|                      |      |
|----------------------|------|
| <b>OA/ID Number:</b> | 9006 |
| <b>FolderID:</b>     |      |

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**Folder Title:**  
Community Comments 11/12/96 [2]

|               |             |                 |               |                  |
|---------------|-------------|-----------------|---------------|------------------|
| <b>Stack:</b> | <b>Row:</b> | <b>Section:</b> | <b>Shelf:</b> | <b>Position:</b> |
| <b>S</b>      | <b>66</b>   | <b>5</b>        | <b>9</b>      | <b>1</b>         |

#### Issues raised by NAPWA

1. Needs a letter from the President to the nation stressing the importance of a continuing, strong national response from government and the private sector.
2. Needs to address the issue of Medicare and Medigap insurance for PLWAs.
3. Needs a greater emphasis on the impact of stigmatization, especially homophobia, racism, and sexism.
4. Wants more emphasis on the quality of life for PWAs.
5. Wants more support for viaticals/accelerated benefits.

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They are service delivery + will continue.

(6) Making/invest in care

ensuring adequate support for essential  
needed health care services funds  
by fed SA, Rx + Rx + Tb Rx + Rx

(7) Ensuring effect P.24

Enhancing IA to CARE Act grantees  
planning councils + consortia.

(8) Improving coord. P.24

Add ~~Tb + SA~~ Rx + Rx among  
people c HIV.

(9) Improving more care P.25

Add CARE Act programs  
to 1st AR

(10) Program of activities P.25

How will this be done

(11) Consider adding STNs to  
Section #.

CAEAR 202-789-3565

Alexander Ro.

Issues - formatting. Mathew -> hard to find  
main subject areas like PX, Research.

② In general, epi. data, fiscal data latest available.

June 30 '96  
FY 97

③ Concern lack of clinical study - women  
- Pediatric indications  
- women included in clinical trials

FDA  
not a lot  
of FDA  
approved

④ P 19 ↑ focus on vulnerable <sup>populations</sup> ~~programs~~.  
↑ federal research.  
Mention non-federal programs.  
Only place non-federal are mentioned.

⑤ p. 21 Grouped Title I + II together.  
Even though services are familiar. Issues  
are different. Ernest Hopkins -> will send language

④ Just four titles are direct service.  
[look @ language ....]

⑥ P 22 Add bullet on SPNS. Mathew - nation's research +  
say SPNS for innovation + replication  
in HIV service delivery. Say how funded -  
90 of each title. Names include some just  
different.

# Document Production

- ▶ Check budget figures - text and appendices
- ▶ Check csc figures - text
- ▶ Timeline

Greg White

Helene

Helene

Lattana

- errata/change sheets for app.
- new figures
- international figure

| November | M  | Tues | Wed | Thurs. | Fri. | Sat. | Sun. |
|----------|----|------|-----|--------|------|------|------|
|          | 18 | 19   | 20  | 21     | 22   | 23   | 24   |
|          | 25 | 26   | 27  | 28     | 29   | 30   | 1    |
|          | 2  |      |     |        |      |      |      |

New version

11/18

ONAP review

11/19

Final changes

11/21

Reproduction/Printer

11/22

Back from reproduction

11/26

▶ Going back to Agencies

Preparation for Cabinet-Level Meeting

- ▶ Briefing materials - Cabinet, Sub-cabinet, POTUS
- ▶ Distribution

**Joint United Nations Programme on HIV/AIDS**

20 Ave Appia  
1211 Geneva, Switzerland

**Date:** Nov 12, 1996

**To:** Paul Bonberg

**Phone:** 202 - 664 - 6300

**Fax:** 202 - 463 - 1135

**From:** Pascale Wortley

**Phone:** 41-22- 791-4474

**Fax:** 41-22- 791-4162

**RE:** International graphics

**Number of pages including cover sheet:** 2

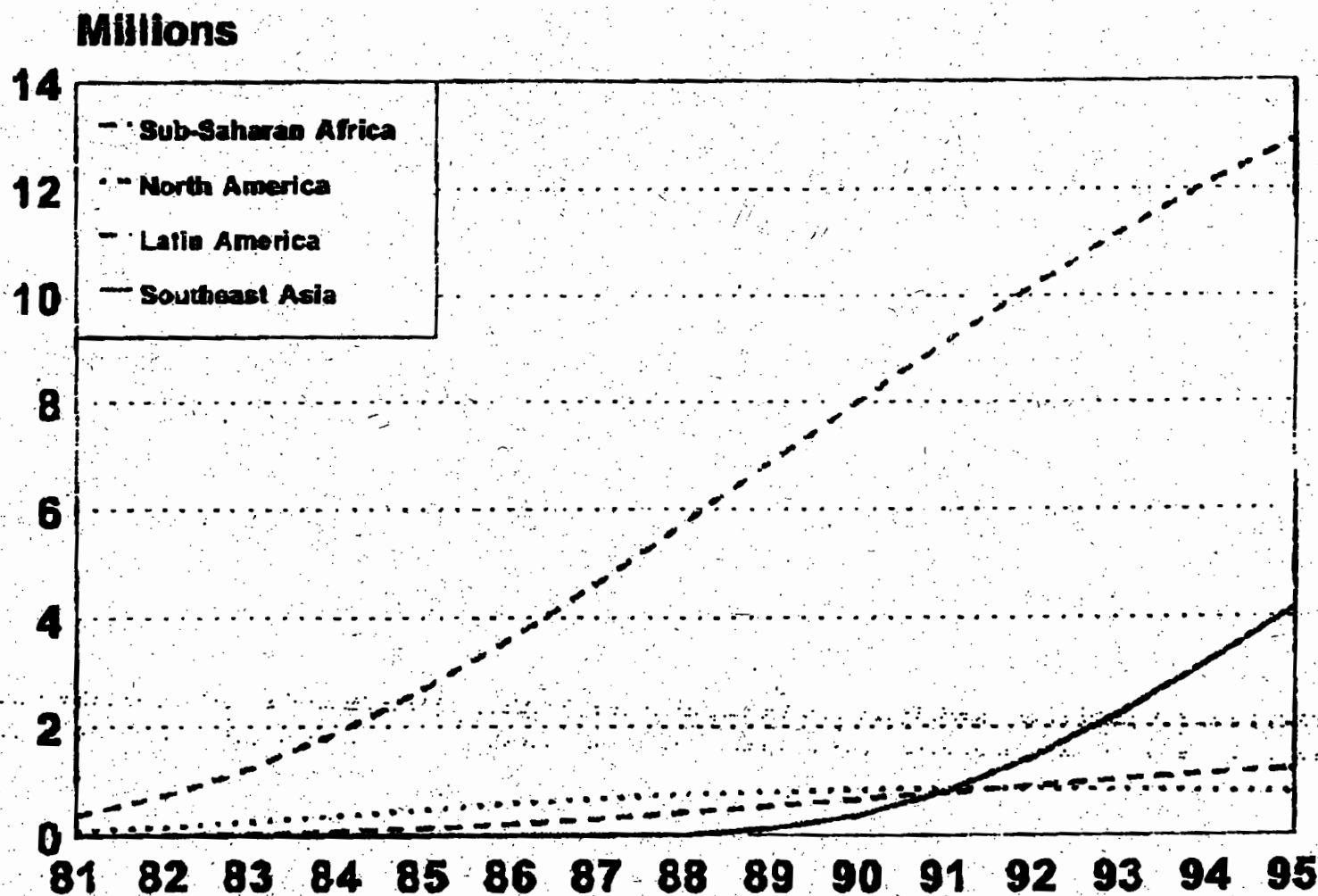
**Message:**

Dear Mr. Bonberg--

Attached is the graph we discussed earlier. It only includes the 4 regions with the highest numbers as the lines for the remaining regions tend to get obscured--We can add them in though if that would be of help.

Pascale Wortley  
4122-791-4474/4678

# Estimated number of adults living with HIV/AIDS in selected regions, 1981-1995



To: Patsy Fleming  
National AIDS Policy Coordinator

From: Paul Boneberg  
Global AIDS Action Network (GAAN)

RE: Draft National AIDS Plan

Date: November 12, 1996

Patsy--

Thank you for the opportunity to comment on the draft national AIDS plan.

Let us begin by again acknowledging the importance of the plan's existence and the inclusion of international issues within it. We recognize that incorporating the complex international aspect is difficult.

We have no objections to what is outlined as the US response to the global pandemic, however we do urge consideration of a few additions and clarifications.

1. Most importantly we urge the inclusion of a statement specifically reiterating the continuing priority of supporting NGOs working in AIDS on the community level. As you know this has been an essential component of US leadership.
2. Also missing is the US commitment to research that has direct impact on our international programs. We urge that our commitment to the development of vaccines, microbicides, and therapeutics that is outlined in the research section be briefly restated in the international program element. To not mention microbicides and vaccines in particular could send the message that the US is lessening its support, which we are sure is not our intent.
3. The section dealing with the skills exchange could be read as limiting domestic NGO involvement to the "Lessons Without Borders" program. We would urge that you make clear that utilizing the expertise of domestic AIDS groups is an element of global AIDS efforts and the "Lessons Without Borders" program is a part--not the entirety-- of that endeavor.
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6. It would be useful if the role of the Department of State could be clarified. We assume that they are the lead agency, particularly in coordinating the US's multiple efforts that are referred to in the final paragraph on international programs.
7. It would be helpful if, in the section on "translating research advances into practice", it could be stated that advances in vaccines and therapeutics would be incorporated in future US international activities.

Thank you for the opportunity to provide input on the draft National AIDS Plan. If we can be of assistance please let us know.

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**Number of pages including cover sheet:** 2

**Message:**

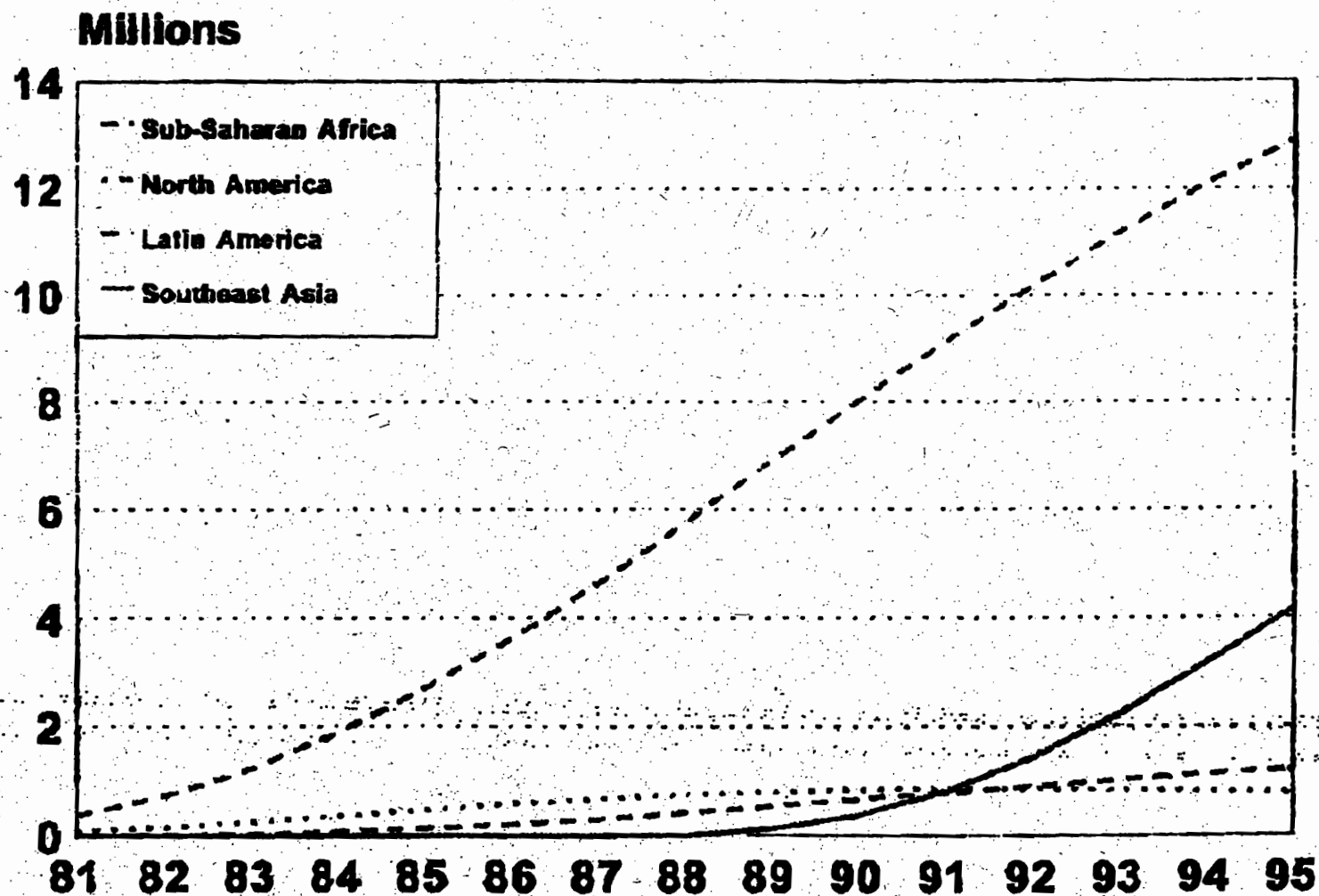
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20 Ave Appia  
1211 Geneva, Switzerland

**Date:** Nov 12, 1996

**To:** Paul Bonoborg

**Phone:** 202-664-6300  
**Fax:** 202-483-1135

**From:** Pascale Wortley

**Phone:** 41-22-791-4474  
**Fax:** 41-22-791-4162

**RE:** International graphics

**Number of pages including cover sheet:** 2

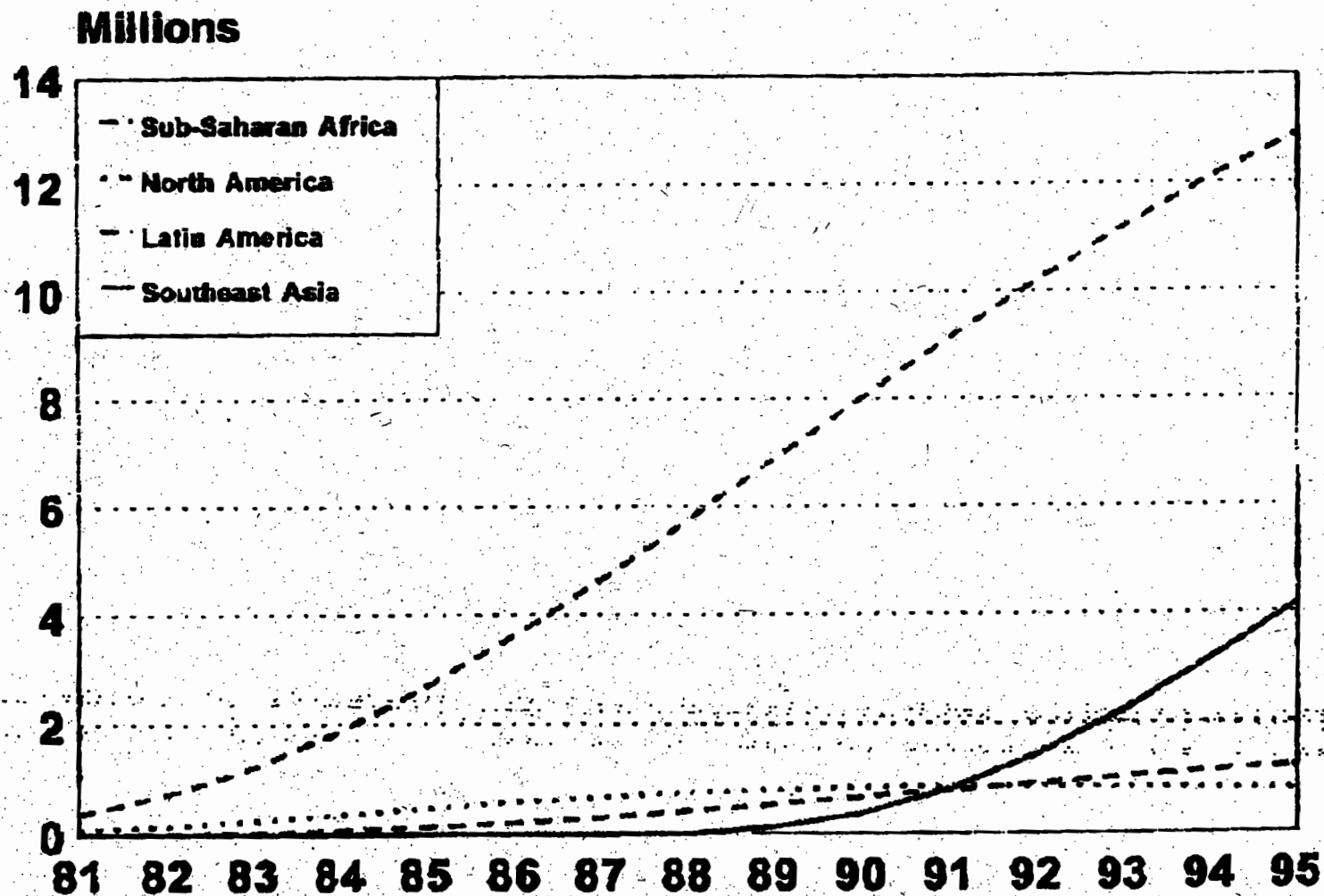
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**From:** Pascale Wortley

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**Fax:** 41-22- 791-4162

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**Number of pages including cover sheet:** 7

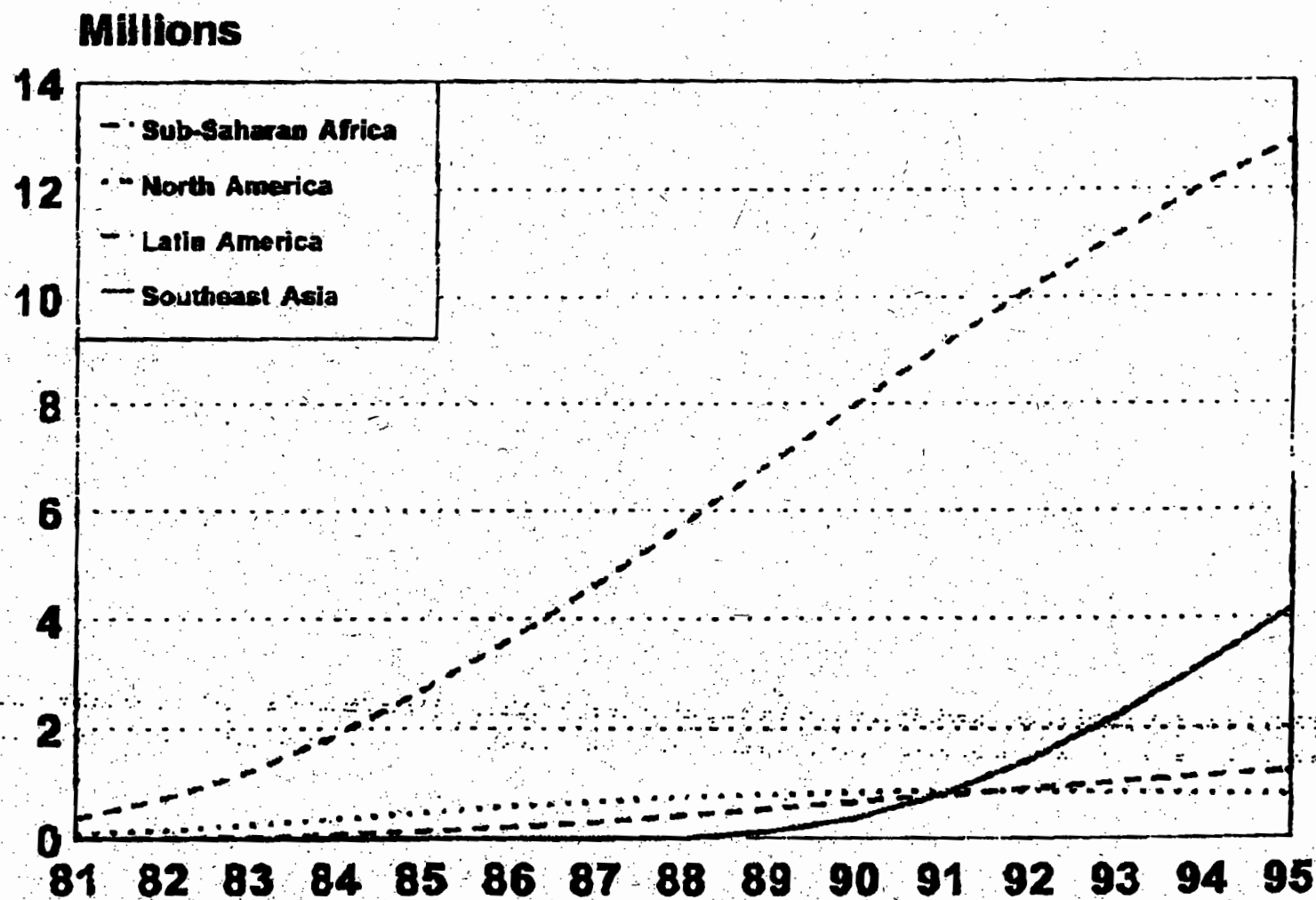
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**Fax:** 41-22-791-4162

**RE:** International graphics

**Number of pages including cover sheet:** 2

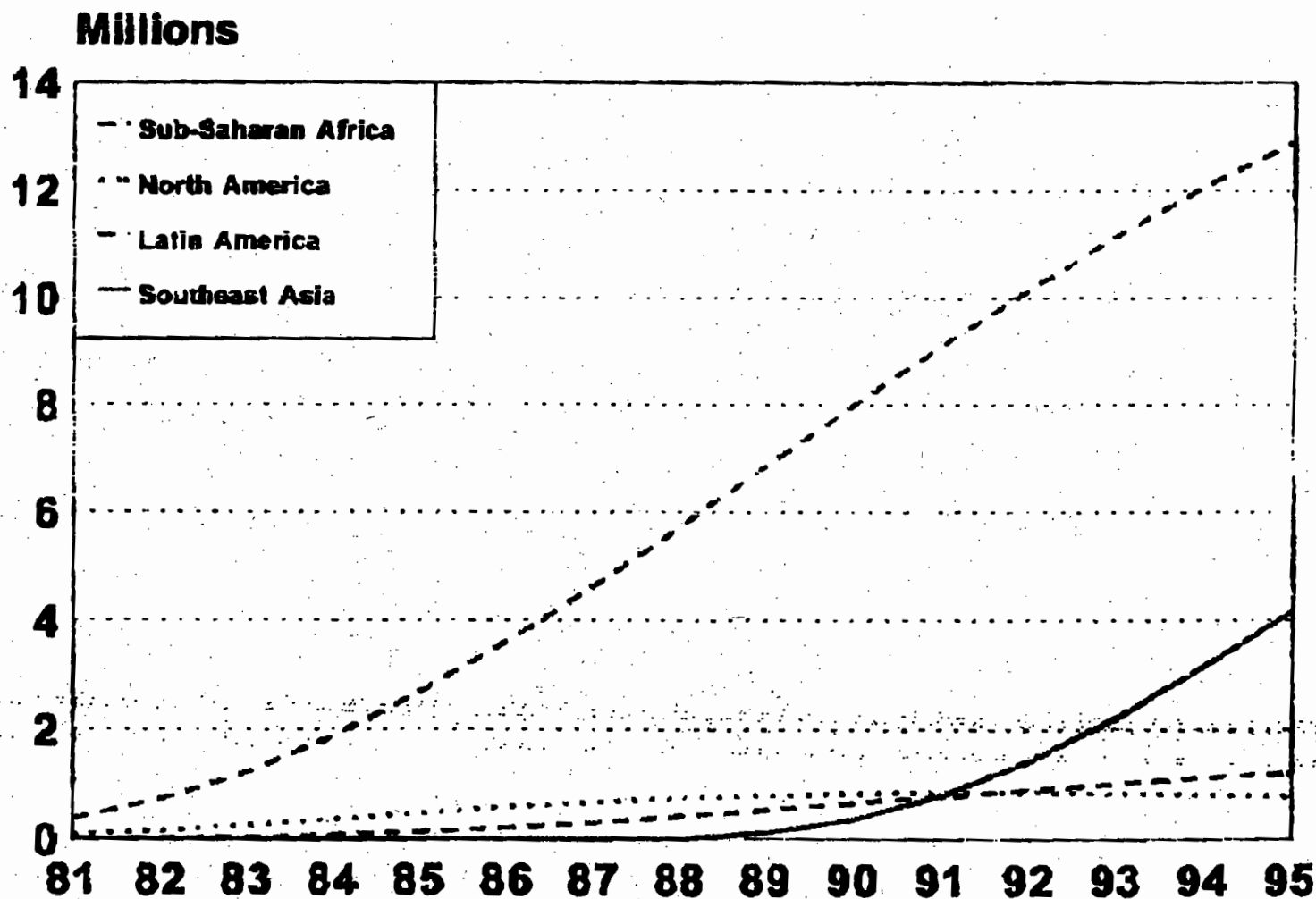
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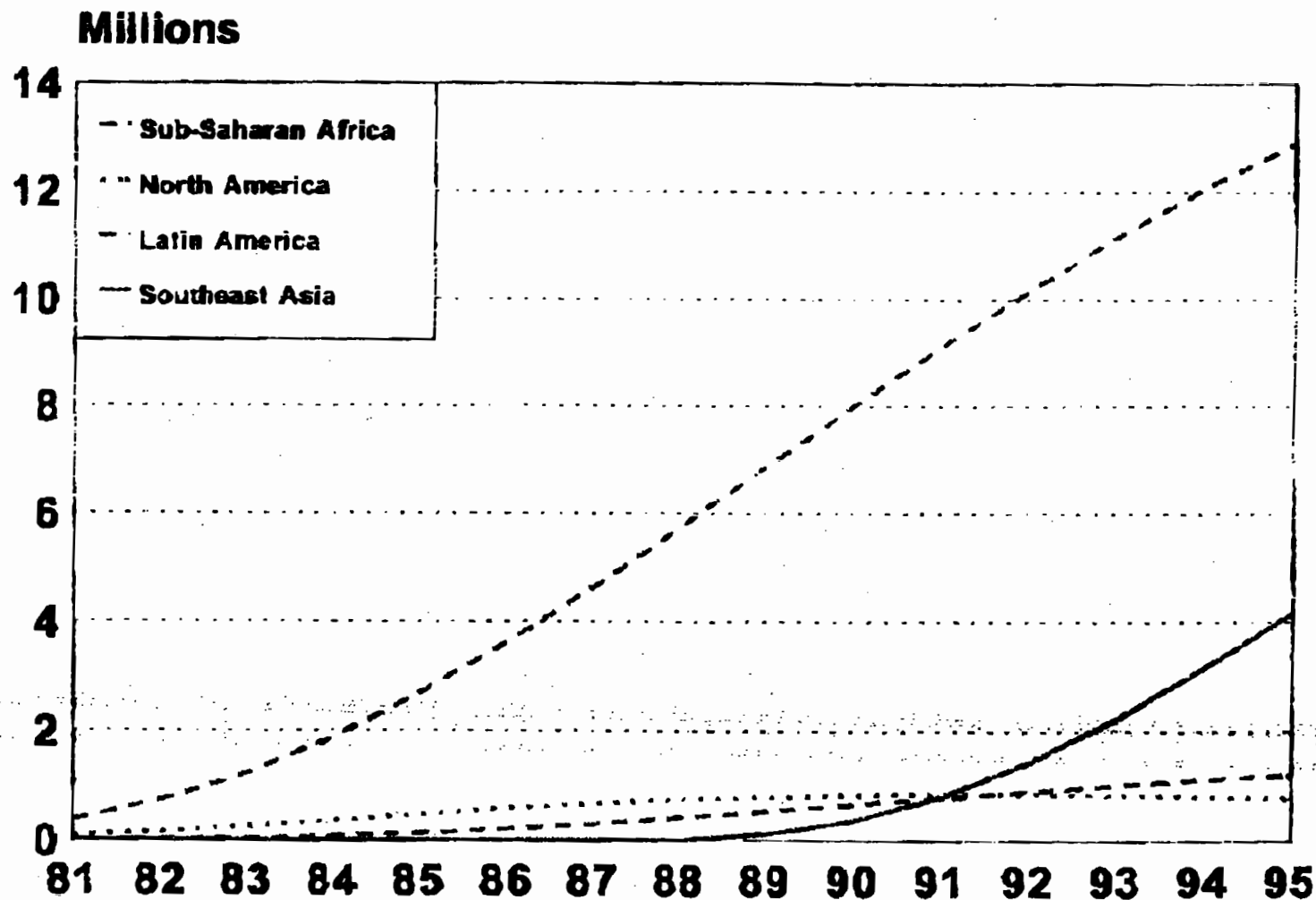
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# Global AIDS Action Network

1931 13th Street N.W. Washington D.C. 20009 202-667-6300 202-483-1135-Fax globalaids@aol.com

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# NASTAD

NATIONAL ALLIANCE OF STATE AND TERRITORIAL AIDS DIRECTORS

## FACSIMILE TRANSMISSION

to  
Patsy Fleming  
Jeff Levi

from  
Julie Scofield

date  
11/12

page/s to follow  
3

- ☐ As requested
- ☐ Review and comment
- ☐ As discussed
- ☐ Please respond
- ☐ For your information

If transmission is not  
complete, please call  
202-434-8090

### comments

- Comments / feedback on PRAT strategy document
- Would like to nail down a meeting with you soon as well -

# NASTAD

## NATIONAL ALLIANCE OF STATE AND TERRITORIAL AIDS DIRECTORS

### MEMORANDUM

November 12, 1996

TO: Patricia S. Fleming, National AIDS Policy Director

FR: Julie M. Scofield and Joseph F. Kelly NASTAD

RE: Comments on The National AIDS Strategy

Thank you for the opportunity to provide comments on the draft document "The National AIDS Strategy." We look forward to meeting with you in the near future to discuss this document and other issues of importance as the Administration prepares for a second term of office.

#### Introduction

We have two brief comments on this section. First, the document should include the most recent figures from CDC on the epidemic. Second, we are troubled by the use of disease comparisons in the discussion of the lifetime cost of medical care. The AIDS community is outraged when other organizations use such comparisons. We feel it is divisive to use these kind of comparisons to justify investments in programs and/or public policy decisions.

#### Prevention

In general, this section adequately lays out a national HIV prevention agenda. We particularly support the references to HIV prevention community planning as the centerpiece of our nation's HIV prevention strategy and recommend that the importance of community planning be recognized throughout this section. Specifically, under the section on primary care, community planning should be referenced in the discussion of our counseling and testing programs. Efforts to target and enhance counseling and testing programs will require discussion and support from community planning groups around the country. In addition, we would like to raise the following concerns with the prevention section.

First, more attention needs to be paid to the prevention of HIV among injection drug users and other substance users. In particular, in the accomplishment section, mention of the Tampa initiative should be included. There should also be a goal specific to prevention of HIV among injection drug users in the section on future opportunities. This is far too important a prevention challenge to be mentioned only within the context of other sections.

Second, there should be a funding initiative for HIV prevention in the section on future opportunities. Additional resources are needed at the local level to implement the high priority prevention programs identified through the community planning process. We do not believe we can accomplish our national HIV prevention goals without additional resources from the federal government.

The reference to the "Congressionally-set goal of reducing perinatal transmission by 50 percent by the year 2000" should be eliminated. This is a glaring oversimplification of the congressional language that fails to recognize the complexity of the issue and the vastly divergent perspectives on the goal itself. This document should not lend credence to language the Administration and other prevention partners had little if any input in crafting.

The language regarding the President's FY 97 budget request should be broadened to include as a priority increasing funding to state and local health departments so that programs benefiting high priority populations, such as those identified by the President, can be implemented.

#### Care and Services

The strategy is lacking in vision and detail in articulating the future progress needed in HIV/AIDS care and services. Although the statements are clear and important on maintaining as investment priorities the Medicaid program and the CARE Act, there is a very limited strategy described for achieving the goals of affordable, high quality, and responsive care services. In our view, the President's strategy speaks too cautiously about the most recent HIV therapies and disease monitoring technologies. Although we agree that long-term clinical effectiveness of combination therapies and protease inhibitors has yet to be fully demonstrated, there is abundant evidence among researchers, clinicians and consumers that there has been a breakthrough in the way in which HIV disease is treated.

These developments have already changed the routine ways in which HIV care is being delivered and paid for by government programs. The draft White House strategy for AIDS care and services pays little attention to the way in which the newest therapies have altered the treatment opportunities for people living with HIV/AIDS and gives no mention to the way in which the scientific breakthrough represented by viral load testing has changed how HIV disease is attacked by medical intervention.

We believe there needs to be a stronger statement of commitment in the President's strategy that articulates the following points:

- access to the latest developments in HIV/AIDS treatment needs to be a high priority to ensure that these breakthrough therapies are not merely available to individuals

with the ability to pay but are affordable and available to those individuals who are uninsured or underinsured.

- viral load testing represents an important new method for monitoring HIV/AIDS treatment and progression of HIV disease and strategies should be developed to ensure that access is provided in the context of high quality primary care services.
- federal agencies should work with states to ensure that state-of-the-art treatment strategies are employed throughout the public and private sector health care settings, including Medicaid managed care and Ryan White settings.
- the federal government, working in partnership with states and the private sector should develop long-term strategies for examining cost-reduction in terms of the new therapies.

### Appendices

We have not had sufficient time to review and comment on the appendices in depth. However, the section of the appendices for HRSA is, in general, woefully inadequate in articulating a vision for delivering HIV/AIDS care for the next several years. The approaches described appear to be a mere fulfillment of the reauthorized CARE Act requirements, and fall short of describing a strategy for ensuring that high quality HIV/AIDS care is affordable, accessible and responsive to the changing treatment dynamics into the next century. The HRSA section could benefit from the kind of goal setting and examination that is described in the section for the Department of Veterans Affairs which appears to reflect a better understanding of the new treatment developments and translating these developments to patients within the VA health system.

Thank you for the opportunity to provide our comments. We look forward to meeting with you as soon as a time can be arranged.



# National Council for International Health

1701 K Street, NW - Suite 600  
Washington, DC 20006-1503 USA  
Tel: 202-833-5900 - Fax: 202-833-0075  
E-mail: <ncih@ncih.org>

## FAX TRANSMITTAL

To: Patsy Fleming  
At: ONAP  
From: Cynthia Mariel  
Dept: AIDS Program

Fax: 202-632-1096  
Tel: \_\_\_\_\_  
Date: 13 Nov 96  
Ext: 209 Pages: 5

## MEMORANDUM



# NATIONAL COUNCIL FOR INTERNATIONAL HEALTH

1701 K STREET, N.W. SUITE 600, WASHINGTON, DC 20006, (202) 833-5900, FAX: (202) 833-0075

12 November 1996

Ms. Patsy Fleming, Director  
Office of National AIDS Policy  
750 17th Street, NW  
Washington, DC 20503

Dear Patsy:

I would like to thank you again for the recent opportunity to meet with you and your staff and to discuss issues related to global AIDS. I look forward to continuing our history of working together to increase support for and enhanced commitment by the United States government to international AIDS efforts. I greatly appreciate your interest in and demonstrated support for global AIDS issues.

As requested, I have reviewed the draft document, *The National AIDS Strategy*, and have enclosed my comments on the second page to this letter. I very much appreciate the efforts of your office to develop this strategy and congratulate you on the production of such a fine document.

I have prepared a few comments that, of course, reflect my position as an organizational representative working in international AIDS. They do not integrate the political and strategic positioning that is inherent with the work of a White House office. Thus, you will need to weigh my comments against the operational mandate and political context of your own office. Please feel free to contact me if you require additional information and/or review.

In addition, I would also like to take this opportunity to make a special request. I would very much like to include an interview with you for our upcoming issue of *AIDSLink*. The interview would be in a written question and answer format and would focus on the activities of your office in regards to international AIDS during the upcoming Administration.

Based largely on our conversation last week, I have prepared several written questions that are enclosed as a separate page of this letter. Please review the questions and then contact me so that I might know if you are available and agreeable to this interview. For purposes of clarity and efficiency, I am simply asking that you prepare a written response to the questions as well as add any additional comments. In order to meet our press deadline, I would need receive your response to the interview questions no later than 25 November 1996.

Thank you again for the opportunity to work with the Office of National AIDS Policy. I look forward to hearing from you in the near future.

Sincerely,

Cynthia E. Mariel  
NCIH AIDS Program



**Comments on the draft copy of  
The National AIDS Strategy**

**1. Page 3, left column, paragraph 1**

Defeating HIV is compared to eradication of smallpox and polio.

**Comment:** Many would argue that such a comparison tends to medicalize HIV when the issue of HIV/AIDS is multi-faceted and goes well beyond a health problem with a medical solution.

**2. Page 5, left column, goal #2**

**Comment:** Because HIV is so closely linked to contextual factors such as socio-economic conditions it might be valuable to include additional wording so that the goal reads, "by providing strong continuing support for effective AIDS prevention efforts and reduction of the socio-economic conditions that contribute to the spread of HIV."

**3. Page 7, right column, final paragraph**

**Comment:** The description of the global AIDS epidemic does not cover areas addressed in the previous paragraphs on domestic AIDS. It might be valuable to include some descriptive information that identifies the percentage of HIV infections globally as compared to the number in the U.S., the percentage of global infections that are among women, the percentage of infections that are via heterosexual transmission, and the care related expenditures by the U.S. government related to international AIDS.

**4. Page 29, right column, final paragraph**

**Comment:** Does more specific descriptive information need to be added when identifying the United States as the largest contributor to international efforts to combat the pandemic of HIV and AIDS? I have previously heard representatives from USAID describe this role in more specific language.

**5. Page 30, right and left column under Future Opportunities for Progress**

**Comment:** In general, the description under this heading focuses on past activities as compared to identification of future commitments. More specifically, in reference to the Paris AIDS Declaration more action oriented language might be included such as, "The U.S. will actively support full enactment of the 1994 Paris AIDS Declaration, of which the U.S. was a signature, through government policies and programs and will encourage other nations to become signatures and supporters of the Paris AIDS Declaration."

**6. Page 30, left column, last paragraph**

**Comment:** It is recommended that another statement be added that indicates that the U.S. needs to strengthen support for global HIV/AIDS activities among U.S.-based private voluntary organizations, nongovernmental organizations in developing countries and global HIV/AIDS networks.

### **Interview questions for *AIDSLink***

1. What do you consider to be the number one priority of your office during the next four years in terms of the US global response to AIDS?
2. How can US-based organizations active in global AIDS efforts assist ONAP in achieving this goal?
3. What contributions can AIDS organizations from developing countries make towards this goal?
4. Why do you think support by the US government to UNAIDS is critical to an effective response to the AIDS pandemic?
5. How can US support for UNAIDS be strengthened?
6. What do you consider the role of your office to be in relationship to major USAID contractors working on international AIDS projects?
7. Why do you think it is important for US-based domestic AIDS groups to become involved in global AIDS?
8. What unique contributions do you believe US-based domestic AIDS groups can make to global AIDS efforts?
9. Based on your knowledge of the US Congress and results of the recent US elections, what are the most effective kinds of educational and advocacy activities that *AIDSLink* readers need to undertake in order to increase support for global AIDS?
10. At present, over 90 % of HIV infection is among developing country populations and yet, approximately only 8 % of global HIV/AIDS funding is spent in developing countries. In addition, per capita health related expenditures by health ministries in many developing countries are less than \$2 per year. How do you reconcile these realities with the strong support you have demonstrated on the issue of equitable access to AIDS treatment and care in developing countries?
11. On World AIDS Day 1994 you were the US representative to the Paris AIDS Summit. At this meeting, the US joined with 42 countries in signing a declaration in which national governments undertook to promote and protect the rights of individuals, particularly people living with HIV/AIDS. To date, the US government still has a travel ban in place restricting people living with HIV/AIDS from entering the country. Will elimination of this restriction be a priority of your office during the next four years?

Additional comments: If the President will be introducing the National AIDS Strategy before December 6, it would be great to include this as an announcement in *AIDSLink* and comments from you on how ONAP will use this strategy in their international AIDS efforts.

NATIONAL AIDS FUND

**FAX TRANSMITTAL**

**DATE:** November 13, 1996

**TO:** Patricia S. Fleming

**FAX:** (202) 632-1096

**FROM:** Callie Gass

**TOTAL PAGES INCLUDING THIS COVER:**

6

**COMMENTS:**

November 12, 1996

BY FAX  
5 Pages

Patricia S. Fleming  
National AIDS Policy Director  
Office of National AIDS Policy  
750 17th Street NW, Suite 600  
Washington DC 20503

Dear Patsy:

Thank you for the opportunity to comment on the draft of the proposed National AIDS Strategy. We are very pleased that the Office of National AIDS Policy has developed a strategy to serve as "a foundation for the Administration's response to the epidemic." The strategic plan is a good statement of where we find ourselves at the moment and allows us to take stock of our accomplishments. It also delineates the large territory we must cover as we struggle to stop the spread of this epidemic and to provide appropriate care and service to those who are living with HIV disease.

Staff at the National AIDS Fund has reviewed the document and has prepared both general comments and specific recommendations for changes and edits for your consideration.

#### PRIVATE SECTOR COLLABORATION

We were very concerned that the draft strategy is silent on the contributions the private sector has made - and is continuing to make - to fighting the HIV epidemic. It seems to us that many of the recent accomplishments were the result of collaboration between the government and the private sector. Moreover, it is our experience that the private sector - particularly private philanthropy - is a key player in many regions of the country, particularly in the field of prevention, and nationwide in supporting research. We also urge you not to overlook the role businesses and unions have played in providing prevention education and in changing the workplace environment to accommodate those living and working with HIV/AIDS.

The following additions to the strategy, which address the ongoing collaboration between the government and the private sector, should be considered:

- o *The Message from the National AIDS Policy Director* should contain a paragraph specifically addressing collaboration with private sector philanthropies and businesses, labor, local communities, and religious organizations, rather than lumping everyone together as "non-governmental." These collaborations have strengthened the effectiveness of federally funded initiatives, created powerful partnerships between the public and private sectors, and generated steady increases in volunteerism and charitable giving; all of which stretches scarce federal resources and improves the climate in which all of us do our work. (Page 4, para. 2)

- o Add a bullet to the "Goals" which establishes collaboration as a goal. *"To harmonize federal initiatives with private sector capacities and commitments to alleviate suffering, reduce infections, and seek practical ways to end the pandemic;"* (Page 5)
- o Add information on the successful use of programs, especially AmeriCorps, to add resources to communities as they fight the epidemic; (Page 9)
- o Add the following bullets to the list of actions since President Clinton took office; (Page 9)
  1. Promoting workplace education through Business/Labor Responds to AIDS;
  2. Attaining FDA approval for home testing.
- o Add the word *workplace* to the third bullet on Page 10 so that it reads *"Strengthening community based and workplace programs;"*
- o Integrate the concept of workplace education and prevention into the discussions on page 12, particularly under the subhead *Prevention Education*
- o *Ensuring Effective Use of Limited Resources* (Page 24) should include a fourth method as follows:  
*(4) and collaborating with the private sector.*
- o The *Record of Accomplishments* should include the BRTA Hotline in the fifth bullet. (Page 33).

#### A. PREVENTION

The strategy in this section is almost a list of all possible things the Administration could do, many of which are clearly out of ONAP's control, such as increasing access to substance abuse treatment and reducing the availability of illegal drugs. All options are given the same importance in the narrative. We recommend that the prevention section emphasize those things which 1) ONAP can reasonably hope to influence and 2) which have a direct and immediate effect on reducing the numbers of transmissions. We believe this strategy should strongly emphasize preventive interventions, -- such as syringe exchange, and the elimination of barriers to those interventions as well as effective prevention education, targeted to vulnerable populations, that results in behavior change/modification -- as top priorities. We believe that these remain the most direct routes to reducing transmission. The strategy and intent should be crystal clear on this point.

## **B. RESEARCH**

### ***Future Opportunities for Progress.***

While the November 1996 Draft Strategy outlines the need for coordination of the *federal* research effort, (page 17) and supports changes at the NIH to help strengthen the *national* vaccine effort, **development of an HIV vaccine will require international cooperation and coordination and additional participation by the private sector.**

The following additions to the Strategy should be considered:

- **state a role for the U.S., perhaps even the President, in the international effort to develop an HIV vaccine (page 17).**

International cooperation and coordination is needed because:

- multiple efficacy trials will be needed and only 1-2 are likely to be done in the U.S. at any point in time;
  - success will depend on protecting individuals from all HIV strains; most HIV strains are just entering the U.S. population, so trials in other countries will be necessary;
  - the recent success in HIV therapeutics will not be of benefit to many people in this country and the world who do not have access to therapy; prevention through vaccination is a more economically feasible strategy for these populations;
  - U.S. dollars invested in developing countries would be better utilized if the AIDS epidemic could be controlled in those countries
- **set a goal of identifying at least a partially effective HIV vaccine by the year 2005 (page 17).**

This goal is appropriate at this time because:

- re-election has been accomplished;
- there is now scientific consensus that an HIV vaccine is possible;
- the first efficacy trial of an HIV vaccine will likely be initiated during the next 4 years; results from this trial would not be available until after the next election so some movement on this topic is virtually assured;
- the recent success in HIV therapeutics has demonstrated what can be accomplished when substantial public and private sector efforts are made;
- the increased private sector involvement necessary for success would be stimulated by Presidential leadership combined with the generally strong economy;
- time is of the essence; the sooner an effective HIV vaccine is found, the sooner the public health benefits and economic savings would accrue to the U.S. and the world.

- **consider specific actions to demonstrate international leadership, coordination and collaboration.**
  - place HIV vaccine development to the G7 agenda to establish a worldwide commitment and strategy (International efforts);
  - work through the World Bank to guarantee loans to developing countries to purchase HIV vaccines (International efforts)
- **commit to a substantial (50-100%) increase in funding for HIV vaccine R&D at the NIH over the next 4 years.**

While it is commendable that this office has taken a strong interest in microbicide research, it could be severely criticized for not taking as active an interest in HIV vaccine development, since vaccines, not microbicides, are a proven, cost effective means for preventing the spread of infectious diseases (page 18). While there is some re-direction of funds at the NIH into vaccine R&D, re-directing existing funds is slow; new funds are needed to adequately stimulate these efforts. Stimulating HIV vaccine research at the NIH will only be half of a successful formula; stimulating private sector investment is also necessary.

- **consider specific actions to attract more private sector involvement in HIV vaccine development:**
  - work with Congress to address issues that impede private sector investment in HIV vaccine development (e.g. liability, patent issues) (page 17).
  - establish a Forum for Collaborative HIV Vaccine Research (page 18) to promote public-private collaboration on AIDS vaccine development, comparable to the one formed for therapeutics research (pg. 19). A separate Forum seems appropriate since the vaccine developers and the issues and obstacles are different from those in HIV therapeutics and since an international perspective is required;
  - consider new models to provide federal funds to stimulate private sector investment in HIV vaccine development.

## E. INTERNATIONAL ACTIVITIES

We believe this section misses a good opportunity to identify the extensive work that has been accomplished on the global impact of the epidemic. The section strikes us as vague and unfocused. The section on USAID would be strengthened by the inclusion of dollar figures and a better description of its cumulative contributions to the global fight. *Future Opportunities for Progress* needs more specific action oriented activities to be useful and given recent events, a commitment to maintain and strengthen the USAID Office on AIDS.

Thank you again for allowing us to comment on your draft document. We hope these comments are helpful as you move towards a final strategy.

If you have any questions or want to discuss these comments further, please give me a call at 202-408-4848, ext 217.

Sincerely,



Callie B. Gass  
Deputy Director, Programs and Partnerships

## MEMORANDUM

**TO:** Patsy Fleming  
Director of National AIDS Policy  
**FROM:** AIDS Action Council  
Christine Lubinski/Jay Coburn  
**RE:** National AIDS Strategy document  
**DATE:** November 14, 1996

---

Thank you for giving us the opportunity to meet with you last week to talk about the priorities of your office for the Administration's second term. We have reviewed the draft "White House National AIDS Strategy 1997" that you gave us at that meeting, and while we wish we had been given more time to review this document, we do appreciate the fact that you sought AIDS Action's input.

We are concerned that the draft document reads much more as a litany of ongoing activities than as a strategic plan for at least the next term of this Administration. The information in the document is not even completely current in terms of accurately reflecting the current funding levels of AIDS programs, and certainly does not reflect a clear articulation of the real challenges that now face us in the context of promising new treatments and their implications for HIV prevention, counseling and testing programs, the whole array of access to care and supportive services programs, including safe and appropriate housing. There is little recognition of the barriers which threaten our progress in the AIDS epidemic from vociferous opposition to the budget authority of the OAR, ongoing efforts to stigmatize and discriminate against people with HIV/AIDS and thereby discourage them from finding out their serostatus and/or seeking care; the increasing fragmentation of the nation's health care systems and cost reduction strategies which threaten quality of and access to health care; and the erosion of any genuine commitment to federal leadership in ensuring that people have housing, just to name a few.

Again, while we appreciate the opportunity to review the draft document, the tight timeline for comments and the absence of any real opportunity for collective dialogue on all of these challenging issues, cannot be construed as real community input. Moreover, the small selection of national groups who received this opportunity, hardly adequately represent the breadth and diversity of the national AIDS community. We thought it was important to review this document and to highlight factual inaccuracies and notable omissions, and have done so (see attached). But we also wish to be clear that even with the integration of the comments provide, it is not our view that this document fulfills its function as a plan for a national AIDS strategy.

## Substantive Edits/Suggestions on Draft "White House National Strategy Plan 1997"

Per your request, AIDS Action Council staff have reviewed the draft National AIDS Strategy and are submitting the following editing comments for your consideration:

### I. Introduction

- The goal to "reduce the number of new HIV infections..." should refer to "continuing support for effective *HIV* prevention efforts;"
- In the section "An Expanding Public Health Threat" on page 6, second paragraph, *gay and bisexual men of color* should be added to the list of populations that are heavily affected today.

### II. Overview of Federal Efforts

- The first paragraph on page 8, second to last sentence, add prevention to read: "In FY 1986 the Federal government expenditures for AIDS research, prevention & **surveillance**, income maintenance, and care were \$508 million."

#### A. Prevention

- Total number of new infection is estimated to be approximately 40,000 to **60,000** people each year.
- On page 9, under "Sentinel accomplishments," fourth bullet, insert community-based to read: "Due in part to successful implementation of CDC-sponsored *community-based* prevention strategies, a slowing in the growth of the epidemic."
- Also on page 9, first column, last bullet, change to read "Launching the AIDS prevention community planning partnership -- empowering local communities to target resources to innovative prevention efforts for communities at risk." Community planning groups do not develop interventions; they are charged with identifying unmet needs and setting priorities.
- Also on page 9, last paragraph, first sentence strike and add: "... are most effective when designed and implemented ~~at a local level~~ *in partnership with communities to whom they are targeted.*"
- The section on "Improving Understanding of Trends in the Epidemic" is very good, particularly the assertion that surveillance can be improved without jeopardizing confidentiality. We insist that you explicitly state strong support for the availability of anonymous testing and opposition to mandatory names reporting.

- The section on "Strengthening Community-Based Programs" is very good.
- The section on "Preventing HIV transmission from the use of contaminated injection equipment" is problematic. While CDC has issued guidelines regarding the use of bleach to clean injection equipment, several studies have seriously questioned the effectiveness of bleach as an realistic prevention strategy. Secondly, is CDC now supporting the removal of restrictions on over-the-counter sale of syringes?
- This document needs to address the issues of partner and spousal notification. We recommend under the section on page 14 "Targeting Vulnerable Populations" a section on partner notification programs. One effective strategy to target vulnerable populations is requiring states to make a good faith effort to notify the spouses of persons with HIV and to have in place voluntary partner notification programs that will protect confidentiality and risk of domestic violence. These voluntary programs should be implemented at the local level and only when they will help change risk behaviors and provide referrals to early intervention and care.

## **B. Research**

- The section, *Contributions of AIDS Research to Research on Other Diseases*, is too general. It would be more powerful if it included more actual and detailed cross-over achievements.
- It should be noted that resistance to OAR and the Consolidated Budget has and will in all likelihood continue to threaten long term planning capacity for all AIDS research at NIH. A clear statement of continued support in the face of that resistance would be helpful.
- In the section detailing the Report of the NIH AIDS Research Program Evaluation Task Force, the recommendation calling for increased research into the causes and treatments of HIV related opportunistic infections should be added.
- On page 18, in the bullet point regarding joint efforts with UNAID, add a commitment to encouraging international efforts in vaccine development and testing protocols.
- On page 19, the last sentence seems to come from nowhere. A sentence should be added that suggests that due to the complexity and expense of new regimens and the damage, over time, caused to an individual's immune system by HIV, even the new therapies and regimens are unlikely to produce positive outcomes for many thousands of people living with HIV/AIDS. Therefore, new drug development must continue to be enthusiastically supported.
- Also on page 19, you state a commitment to the continuation of the CPCRA. If the Levine recommendation regarding the collapse of clinical trial networks is implemented, will the CPCRA continue in its present form?

- The final paragraph in the Research section is unclear. The research conducted at DOD, CDC, and the VA should be defined and the \$4 million for AIDS research government wide should be more clearly characterized.

### C. Care

#### Ryan White CARE Act & Housing

- On page 21, the bullet on Titles I and II needs to include insurance continuations and home and community-based care. On page 22, Title V also supports SPNS, which includes ongoing service delivery for Native American populations.
- There is no mention of targeting care services to communities and populations in greatest need or who require services that are culturally relevant such as people of color, women and adolescents. On page 23 "Future Opportunities for Progress" under *Ensuring Effective Use of Limited Funds* reference to the need to target funding and ensure that services reach marginalized communities should be included. To maximize federal dollars, funds must go to those communities and/or groups bearing the brunt of the epidemic and that are in most need of care services. These federal funds would not only provide immediate care services but also provide funding for the development of basic health care delivery infrastructure and programs that are culturally and age sensitive. Although the CARE Act already includes variables that factor in increased need, greater emphasis on addressing the needs of these communities by HRSA is still needed. These communities include people of color in general, women of color and adolescents. Communities of color currently make up over 53% of the cumulative AIDS case count. Women of color make up over 75.4% of AIDS cases among women yet only represent approximately 20% of all women. More than half of all new HIV infections occur in adolescents and young adults.
- References to FY 97 funding levels for the CARE Act must be revised. On page 24 FY 97 funding for the CARE should be \$996 million and HOPWA should be added at \$196.0 million.
- References to the housing needs of people with AIDS are inadequate throughout the document. The changing demographics of the epidemic are reflected in the growing number of individuals and families living with HIV disease who are homeless or near-homeless. Without stable housing, these people cannot access care or promising drug therapies. Moreover, a significant number of homeless individuals are "dually and triply diagnosed" -- *i.e.*, have chemical addictions and/or mental illness in addition to HIV disease -- and require housing linked with intensive supportive services. In particular, housing should be included on page 5 as a critical component of access to care.
- The list of housing programs on page 22 does not include the McKinney Homeless assistance grants or the Section 8 Rental Assistance programs, both of which are as important (if not more important in some areas) than Section 811 housing.

- The Housing Opportunities for People with AIDS Program (HOPWA) is currently not authorized. Reauthorization HOPWA must be a priority for the Administration. On page 24 "Expanding Support for Housing Services" paragraph insert a commitment to a speedy reauthorization so that program is in place to serve people with HIV/AIDS.

### Medicaid

- We have updated statistics from Kaiser on the importance of Medicaid for people living with HIV/AIDS. Currently, approximately 53% (estimated 90,000 in 1994) of adult Americans and more than 90% of children living with HIV/AIDS receive their medical coverage through Medicaid.
- In the "preserving Medicaid" paragraph under "Future Opportunities", we think you should emphasize why people with HIV disease turn to Medicaid. Obviously, Medicaid is the safety net for the poor, but the point is that many people are impoverished by the costs of medical care for HIV disease and have no other alternative but to turn to Medicaid. The inadequacies and inequities of private health insurance coverage for HIV disease -- both managed care and fee-for-service plans -- plays a major role in this scenario. (caps, lifetime limits, restricted access to prescription drug services, etc.)
- The Administration should be actively exploring avenues to provide Medicaid coverage for PLWHIV as soon as they become medically needy, as opposed to requiring them to become completely disabled and/or impoverished.

### Medicare

- There should be a separate section on Medicare, which is becoming a payer of HIV care for a growing number of people who are living longer with HIV disease and AIDS. Limitations on what benefits are covered under Medicare (no prescription drugs) and limitations on eligibility for supplementary coverage, which is generally not available to those qualifying for medicare based on disability (as opposed to age), should be addressed.

### SSA Programs

- Language should be included about ensuring that hard-won expansions in the SSDI HIV disability criteria are not undermined. Eligibility criteria must be flexible enough to address the unique nature of disease progression and disability in people living with HIV disease.

### Improving Quality of Care

- There should be a discrete sub-heading on **managed care** quality standards and regulations in light of the increase in managed care in Medicaid, Medicare, and the private market and the need to ensure that quality and comprehensiveness of health care for PWLHIV is not compromised. HCFA's oversight of state medicaid waiver applications might be cited as a vehicle for managed care oversight, for example. The Administration should also be advocating for strong consumer protections in all managed care plans. Of particular interest to people living with HIV/AIDS are the following issues: gag rules, confidentiality, grievance procedures/disenrollment, choice of provider, out-of plan options, prescription drug coverage.
- The Improving Quality of Care paragraph could be strengthened to include references to quality of benefits and services available to people living with HIV/AIDS. (For example, supporting efforts to expand access to Medigap to under 65 disabled populations eligible for Medicare as discussed earlier.)
- There should be a discrete sub-heading on **private health insurance** which could outline some of the benefits/limitations of Kennedy-Kassebaum legislation. There should be at least some discussion about exploring avenues to make private health insurance coverage more accessible and affordable for PWLHIV (and other chronic illnesses).

### **D. Civil Rights**

- There is no reference to the reauthorization of the Rehabilitation Act and the important protections it provides in the "Future Opportunities" section.
- This section should also include protecting the privacy of personal health information and medical records.
- There is no reference to the importance of fighting discrimination in housing. Citing litigation to ensure "access to nursing homes" only emphasizes the glaring lack of attention to the importance of housing for accessing care and enhancing the quality and duration of life for people living with HIV/AIDS.
- The reference to the HIV/AIDS education program for Federal workers on page 27 should be changed to indicate that the program contained information on how to manage Federal employees who have HIV infection.
- The section "Protecting Workers" (p. 27) should include reference to unjustifiable restrictions on Federal employees, Foreign Service Officers and members of the armed forces who have HIV. We recommend adding: The Director of the Office of National AIDS Policy will work with Federal Agencies to examine policies and eliminate provisions that permit discrimination in promotion and retention based on HIV status.

## **E. International Activities**

- The vaccine and microbicide sections of the Research section should be repeated in this Section with an explanation that lays out the difficulties of treating HIV throughout most of the developing world.
- In the *Sharing Technologies* sub-section, the Administration should define a commitment to work with a wide range of domestic NGO's through a wide range of programmatic mechanisms. If for example, a community based NGO in Cleveland has a particular expertise in an important prevention technology, the government should look to that NGO as a potential contractee for sharing technology. "Lessons Without Borders", a showcase program with very little funding, limits these interactions. If all domestic NGOs -- and not a few large inside the beltway NGOs -- were considered for all information and technology exchange contracts, the goals of the program could be achieved without new funding.
- The maps detailing the spread of the American epidemic are very effective. Are similar maps available for the international epidemic? It could be very powerful to show entire African or Asian countries that look like New York.

## **F. Translation of Research Advances into Practice**

- Translation of research advances is vital and we commend you for making this a specific area addressed in the National Strategy. We have learned over the past fifteen years that prevention, care and research programs that are grounded in the communities most effected by HIV will be the most successful. However, it is vital that communities have the resources and tools, including cutting-edge research findings, to be effective.

Translation is often achieved by policies and programs that closely link research and practice. However, translation in the context of linkages between researchers and care/service providers is primarily seen as a one way street--getting good science into the hands of community-based providers. We believe that the relationship is and should be more symbiotic. Partnerships between science and practice not only results in better programs, but also better science. The focus of this section should be balanced to incorporate the complimentary goals of translating research advances into practice and incorporating the needs of care/service providers in formulating research questions and setting priorities.

- An additional or substitute example of the importance of translation should be included. The work of NIH, CDC and FDA around the effectiveness of latex condoms in the prevention of HIV is very compelling and highlights action that will prevent the transmission of HIV to millions of Americans. This partnership provided clear guidance on the effectiveness of condoms in preventing HIV, supported the development of PSAs promoting the correct and consistent use of condoms and provided public health experts

with the leadership and science needed to make condoms available in controversial settings such as prisons, and school-based HIV prevention programs.

***The National AIDS Strategy  
November 1996 Draft***

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**The  
National  
AIDS  
Strategy  
Draft**

**November 1996**

*Version to 1  
Community*

***"We'll keep going until normal life is returned to people who have HIV."***

**President Clinton, August 29, 1996  
Acceptance Speech before the Democratic National Convention**

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

The epidemic of HIV and AIDS constitutes a public health crisis of unprecedented proportions. After 15 years, this terrible national tragedy has affected -- and will continue to affect -- far too many people in the U.S. and around the world. HIV is a disease that we can defeat -- just as we have eradicated smallpox from our planet and polio from the western hemisphere. We have made tremendous progress in our understanding of HIV and HIV disease, ways in which we can treat those who are infected, and the means by which we can prevent infection. We also have more work to do. The National AIDS Strategy provides a foundation for the continuing public-private partnerships that are essential to our success in ending this epidemic.

In 1993, the Office of National AIDS Policy (ONAP) was created by President Clinton to provide a national focus and direction for the U.S. government's response to HIV and AIDS. More recently, President Clinton asked ONAP to develop a comprehensive National AIDS Strategy that would detail the Federal government's long-term approach to this epidemic. The National AIDS Strategy has been developed by the Clinton Administration to capitalize upon progress already made in fighting the epidemic and to catalyze collaborative efforts among Federal Agencies, communities, State and local governments, businesses, schools, churches, families, and individuals.

This document is a snapshot of where we

are as a Nation and where we need to go in achieving these national goals and in ultimately ending the epidemic. It summarizes some of the key accomplishments of our Nation's scientific and public health professionals and identifies key areas for further effort. In addition, the appendices to this report lay out, for the first time, detailed descriptions of the objectives, goals, and budgets of all Agencies involved in the Federal response to HIV in six major areas of HIV policy: prevention, research, care and services, civil rights, international activities, and translation of research advances into practice.

The National AIDS Strategy sets forth a framework and identifies opportunities for progress that will serve as the foundation for the Administration's response to the epidemic in the years ahead. An implementation process for defining specifically how to reach these goals will be a joint effort of the Interdepartmental Task Force on HIV and AIDS, the Presidential Advisory Council on HIV and AIDS, the private sector, and the community. These formal and systematic consultations will be integral to identifying and implementing solutions. Moreover, the National AIDS Strategy is intended to be a living document that requires regular updating and adjustment as goals are reached and new challenges emerge.

The development of a National AIDS Strategy is an historic undertaking. No previous Administration has undertaken so broad a planning effort that: (1) involves all

***The National AIDS Strategy***  
***November 1996 Draft***

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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 Federal government should focus its efforts.

The National AIDS Strategy was drafted in consultation with, and with guidance from, numerous groups and individuals. Within the Federal government, this effort began at the Agency level. Members of the Interdepartmental Task Force on HIV and AIDS (IDTF), representing all Federal Agencies involved in the national response to HIV and AIDS, identified their HIV-related goals, objectives, and highlighted areas requiring special attention. Individuals living with HIV and AIDS, their families, friends, loved ones, and care givers made vital contributions to this Strategy. Numerous non-governmental groups and organizations have also been consulted, including the Presidential Advisory Council on HIV/AIDS, participants in the White House Conference on HIV and AIDS, the ONAP-sponsored regional briefings, patient and consumer advocates, health care professionals, community-based organizations, educators, religious leaders, and business leaders. Earlier insights provided by the National Commission on AIDS, the Institute of Medicine and National Research Council, the General Accounting Office, and the Office of Technology Assessment also have been extraordinarily helpful in developing the National AIDS Strategy.

We face great challenges as a Nation. We are also facing great opportunities.

Together, with steadfast commitment, courage, and leadership, we will win the battle against HIV and AIDS.

Patricia S. Fleming  
National AIDS Policy Director

*"For nearly every American with eyes and ears open, the face of AIDS is no longer the face of a stranger. Millions and millions of us have now stood at the bedside of a dying friend and grieved. Millions and millions of us now know people who have had AIDS and who have died of it who are both gay and heterosexual. Millions and millions of us are now forced to admit that this is a problem which has diminished the life of every American."*

President Clinton, December 1, 1993  
Georgetown University

## **I. INTRODUCTION**

### ***Goals of the National Strategy***

The President has identified the following national goals to guide our efforts to end the epidemic of HIV and AIDS:

- To develop more effective treatments, a preventive vaccine to protect the uninfected, and a cure for those currently infected through strong continuing support for HIV-related research;
- To reduce the number of new HIV infections in adults and children in the U.S. and worldwide until the rate of new infections reaches zero by providing strong continuing support for effective AIDS prevention efforts;
- To ensure that all people living

with HIV have access to services that are affordable, of high quality, and responsive to their needs;

- To ensure that all people living with HIV are not subject to discrimination;
- To provide strong continuing support for international efforts to address the HIV epidemic; and,
- To ensure that research advances are translated into improved HIV prevention programs and enhanced care for HIV- positive persons.

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

The epidemic 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 around the world. While significant progress has been made in understanding the disease and developing treatments since the first case was reported in the U.S. in June 1981, 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 average of 100 Americans are diagnosed with AIDS every day and a similar number of men, women, and children become infected with HIV every 24 hours.

Globally, 8,500 people become infected each day.

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

As of December 1995, the Centers for Disease Control and Prevention (CDC) had received reports of 513,486 cases of AIDS among persons in the U.S. and 319,849 of these persons have been reported to have died as a result of complications related to HIV. Since 1987, AIDS has risen from being the 15th cause of death among all Americans to the 8th. AIDS is now the leading cause of death among Americans aged 25 to 44 (See Figure 1). In 1995 alone, approximately 74,000 new cases of AIDS were reported in the U.S. and more than 46,000 AIDS related deaths were reported to the CDC in 1994. CDC estimates that between 40,000 and 60,000 Americans are becoming newly infected with HIV each year, and that between 650,000 and 900,000 Americans are currently living with HIV.

As the epidemic in the United States has expanded, the demographics of the epidemic have changed. The early years of the epidemic were dominated by cases involving gay or bisexual men living in major urban centers (e.g., New York, San Francisco, and Los Angeles). Today, this group represents less than half of all new cases, although it still represents a majority of persons living with HIV and AIDS. Among the populations that are heavily affected today are young gay and bisexual men, women, and injecting drug users and their sexual partners as well as users of non-

injecting drugs (e.g., crack cocaine and alcohol). In 1995, nearly 14,000 women were reported to CDC as having been diagnosed with AIDS. Women now comprise 14 percent of cumulatively reported AIDS cases. If this trend continues, it is estimated that 80,000 American children will have been orphaned as a result of AIDS by the end of this decade. In 1995, approximately 800 new cases of pediatric AIDS cases were reported.<sup>1</sup>

Adolescents (age 13-19) are increasingly at risk for HIV infection. CDC estimates that one-quarter of new HIV infections in the U.S. occur among people under age 21. A significant number of young people are engaging at earlier ages in sexual intercourse and drug and alcohol use. This fact, coupled with the disturbing number of adolescents who are prone to high-risk behavior due to homelessness, sexual abuse, and other circumstances, makes young Americans extremely vulnerable to HIV infection.

Racial and ethnic minorities have been disproportionately affected by the epidemic of HIV and AIDS. African-Americans, who represent approximately 12 percent of the U.S. population, accounted for 40 percent of newly reported AIDS cases in 1995. Hispanics, who account for about 9 percent of the general population, represented 19 percent of new cases reported in 1995. The number of African-Americans and Hispanics affected by HIV and AIDS has risen dramatically. In 1982, Blacks and Hispanics represented 31 percent of all AIDS cases;

however, as of December 1995, these groups comprised 52 percent of cumulative AIDS cases.

The HIV epidemic continues to spread into suburban and rural areas, with dramatic increases in certain regions of the South and Midwest. Between January 1993 and December 1995 the largest numbers of AIDS cases (86,462) were reported from the South.<sup>2</sup> While most cases are still reported from urban areas, the rate of reported cases in non-metropolitan areas is increasing more rapidly than in urban areas. AIDS cases now have been reported in all 50 States, the District of Columbia, Puerto Rico, Guam, and each of the U.S. territories (See Figure 2).

Average lifetime cost of medical care after an HIV diagnosis is \$119,000.<sup>3</sup> For heart disease and cancer the comparable figures are \$61,211<sup>4</sup> and \$25,000 to \$84,000<sup>5</sup>, respectively. With the development of protease inhibitors, treatment for HIV and AIDS is \$10,000 to \$18,000 per life-year gained. For coronary artery bypass surgery the cost per life-year saved is \$113,000.<sup>6</sup> People living with HIV are disproportionately dependent on the public sector for their health care. More than 50 percent of people living with AIDS are enrolled in Medicaid, including more than 90 percent of children with AIDS. In FY 1996, the Federal government spent an estimated \$1.8 billion on Medicaid benefits for people living with HIV and AIDS and another \$690 million on Medicare benefits. Social Security benefits for people disabled by HIV/AIDS totaled nearly \$1.1 billion in

FY 1996. Many Federal programs such as HOPWA and CDC's prevention efforts contribute to reducing the short- and long-term economic costs of the epidemic.

Globally, the toll of the epidemic is much greater and threatens to reverse decades of economic and public health progress in developing countries. The Joint United Programme on HIV and AIDS (UNAIDS) and the World Health Organization (WHO) estimate that 27.9 million people have been infected with HIV. Since the beginning of the pandemic, 6 million people, including 1.6 million children, have been diagnosed with AIDS. By the year 2000, WHO projects that between 30 million and 40 million people will have been infected with HIV and 10 million to 15 million children will be orphaned due to AIDS.

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

The scope and nature of the HIV/AIDS epidemic have drawn States, local governments, schools, academic institutions, private foundations, health care institutions, business leaders, community-based organizations, and the Federal government into many HIV-related activities. The Federal government, through its public health responsibilities in areas such as research, prevention, health care, and housing has seen a dramatic increase in its activities since the beginning of the epidemic. In FY 1986 the Federal government expenditures for AIDS research, surveillance, income maintenance, and care were \$508 million. By FY 1995 that figure reached \$6.8 billion.

In the past four years, under the leadership of President Clinton, the Administration has increased spending for AIDS research, prevention, income maintenance, and care by approximately 50 percent. Funding for the Ryan White Comprehensive AIDS Resources Emergency (CARE) Act has increased by 158 percent since FY 1993. Support for housing for people living with AIDS has increased by 96 percent in the same time period. AIDS-related research funding budget has increased by 40 percent and AIDS prevention funding has increased by 24 percent. The National Institutes of Health Revitalization Act of 1993 provided the Office of AIDS Research with enhanced authority to develop and implement an annual AIDS research plan and budget.

Approval of AIDS drugs by the Food and Drug Administration has been further accelerated. A community-based AIDS prevention planning process has empowered local communities to develop innovative AIDS prevention programs. Eligibility for Social Security disability benefits for people with AIDS has been simplified and Federal laws prohibiting discrimination against people living with HIV and AIDS have been vigorously enforced.

As the epidemic continues, we must renew our vision for ending this epidemic. The sections that follow focus on six major policy areas: prevention, research, care and services, civil rights, international activities, and the translation of research advances into practice. They identify recent progress and future opportunities for further progress.

### **A. PREVENTION**

*"We have to set a goal. . . We have to reduce the number of new infections each and every year until there are no more new infections."*

**President Clinton, December 5, 1995  
The White House Conference  
on HIV and AIDS**

### ***Record of Accomplishment***

Since the epidemic began, there has been important progress in preventing HIV infection. Early in the epidemic, CDC estimated that more than 100,000 Americans were becoming infected with HIV each year; today, that total is estimated to be

approximately 40,000 people each year.

Sentinel accomplishments in prevention of HIV include:

- Publication in *Morbidity and Mortality Weekly Report* by the Centers for Disease Control and Prevention (CDC) in 1981 of the first AIDS cases;
- Identification in 1981 by the Centers for Disease Control and Prevention (CDC) of the risk factors associated with HIV infection;
- Due to NIH-sponsored research, demonstration that administration of AZT can prevent transmission of HIV from an infected mother to her newborn; and,
- Due in part to successful implementation of CDC-sponsored prevention strategies, a slowing in the growth of the epidemic.

Since President Clinton took office in 1993, efforts in HIV prevention have been accelerated. Actions include:

- Increasing funding for AIDS prevention at CDC by 24 percent (since FY 1993);
- Launching the AIDS prevention community planning partnership -- empowering local communities to develop innovative prevention efforts;

- Launching the Prevention Marketing Initiative, focusing on young adults (18 to 25) with frank public service announcements advocating sexual abstinence and, for the first time, the correct and consistent use of latex condoms; and,
- Reorganizing AIDS prevention efforts at the Centers for Disease Control and Prevention to foster greater coordination of efforts to reduce sexually transmitted diseases and tuberculosis.

Federal agencies have been instrumental in expanding our knowledge base about HIV prevention (see Appendix A). CDC, the Agency with primary Federal HIV surveillance and prevention responsibilities, has been pivotal in identifying risk factors associated with HIV transmission, seroprevalence of HIV in society, and trends in HIV infection and AIDS.

Federal efforts have shown that HIV prevention programs can be effective. CDC's prevention projects, many in partnership with states, local governments, schools, and community-based organizations, have demonstrated that prevention programs are most effective when designed and implemented at a local level. Biomedical, behavioral, and social science prevention research, including epidemiological and natural history studies, conducted and supported by the National Institutes of Health (NIH) and CDC has expanded and will continue to expand our understanding of HIV transmission and the

determinants of HIV-related risk behavior.

The Nation also has combatted the dual epidemics of HIV and drug abuse. The National Institute on Drug Abuse (NIDA), the Substance Abuse and Mental Health Services Administration (SAMHSA), and CDC support efforts to prevent HIV infection among drug users and their sexual partners. The White House Office of National Drug Control Policy (ONDCP) has pursued and coordinated efforts to combat the problem of substance abuse and its devastating consequences.

There have been advances in integrating primary prevention into health care service systems. The Health Resources and Services Administration (HRSA) and the Department of Veterans Affairs (VA) have encouraged broader access to AIDS prevention information through the integration of prevention interventions into primary health care services and through support of early intervention services. HRSA and HCFA have also undertaken special initiatives designed to reduce perinatal transmission of HIV and HRSA has promoted primary prevention through the training of health professionals in the AIDS Education and Training Centers program.

### ***Future Opportunities for Progress***

To achieve the national goal of no new infections requires efforts in the prevention area on five fronts:

- Improving understanding of trends in HIV transmission, seroprevalence, and risk behaviors;
- Improving scientific knowledge about effective prevention models and strategies;
- Strengthening community-based programs;
- Integrating HIV and other prevention efforts;
- Targeting vulnerable populations; and,
- Improving integration of prevention into primary care and improving linkages between counseling and testing and primary care.

#### ■ ***Improving Understanding of Trends in the Epidemic***

Understanding who is becoming infected and through what behaviors is critical to designing effective HIV prevention interventions, as well as for targeting appropriate service resources. As discussed in the introduction, the demographics of the epidemic are evolving, and effective prevention depends on rapidly understanding these shifts and responding to them.

CDC's AIDS case and case death reporting system provides important data for assessing AIDS prevalence and mortality by gender, race/ethnicity, age, and mode of exposure.

However, this approach does not capture sufficient "front-end" information on the incidence and prevalence of HIV prior to an AIDS diagnosis. Therefore, we miss critical warning signs about new trends in affected populations and increasing risky behaviors.

To address this concern, CDC will work to improve its surveillance of HIV infection and related diseases and surveillance of HIV behavioral risk factors both to better monitor the course of the epidemic and to provide guidance to community planners for targeting prevention and service dollars. This can and will be undertaken without compromising the confidentiality of those involved.

■ ***Research on Effective Prevention Strategies***

Effective interventions must be based on sound research findings and evaluations. In response to the recommendations from the Report of the NIH AIDS Research Program Evaluation Task Force, NIH is developing a comprehensive HIV prevention science agenda. NIH and CDC are both committed to increasing future support for basic research on behavior, interventions, social marketing, and program evaluation.

***Behavioral Research.*** Basic behavioral research answers key questions about the determinants of HIV-associated sexual and drug-using behaviors. We still lack critical knowledge in this area, which is central to developing effective interventions.

***Intervention Research.*** Intervention research focuses on individual and community level interventions that result in modified sexual and drug-using behaviors and, as a consequence, reduced HIV transmission. There have been significant accomplishments in this area, but, as this portfolio expands, it will be critical to assess interventions in the context of community cultures and social networks that are relevant to the growing number of populations that must be reached by HIV prevention programs. This research should be designed by a broad range of scientists, public health and community experts to assure its relevance.

***Social Marketing Research.*** The use of social marketing techniques is a relatively new approach to HIV prevention. This promising area requires use of basic and intervention research, as well as careful design and evaluation of social marketing efforts.

***Evaluation.*** To ensure that prevention programs actually are working -- and to ensure that scarce resources are spent on the most effective interventions -- all Federally-funded prevention activities routinely will include evaluation components. Funding Agencies will share widely the knowledge gained about what works and what does not work to ensure promotion of innovation and best practices in the field. In addition, as part of the Federal government's compliance with the Government Performance and Results Act, CDC and SAMHSA will

continue to work with their grantees to develop appropriate performance measures for HIV prevention programs, including those developed under the community planning process.

■ ***Strengthening Community-Based Programs***

Community prevention planning is one of the key innovations in CDC's prevention programming over the last several years. This public-private partnership puts Federal funds to work based on locally-designed priorities. This three-year-old initiative is at a crucial stage of development, and ensuring its success is the third key element of this Strategy's prevention agenda.

Community planning requires ongoing leadership from CDC and its partners as well as the resources to provide the technical assistance the community planning process needs to flourish. Successful HIV prevention often depends on small, new, community-based organizations, many serving minority populations. These organizations need assistance not only on how to plan and compete successfully for available resources but also how to appropriately incorporate epidemiological and research information into community prevention programs.

■ ***Program Integration and Collaboration***

The fourth component of the prevention agenda is improving the integration of HIV prevention into other program areas that

reach individuals at risk for HIV. HIV prevention programs cannot stand apart from other related public health efforts.

***Prevention Education.*** Collaboration with communities and schools is a critical factor in communicating HIV prevention messages to our youth. The Centers for Disease Control and Prevention's *Guidelines for Effective School Health Programs to Prevent the Spread of AIDS* helps assure that young people understand the nature of the HIV epidemic and the specific actions they can take to prevent HIV infection. Strong support for these programs should and will continue.

***Substance Abuse.*** HIV transmission is closely related to substance abuse, through needle-sharing behaviors, as sex is traded for drugs, and as drug and alcohol use impairs judgment and increases risk-taking behaviors. Breaking these linkages will require:

- *Integration of HIV prevention into substance abuse treatment and prevention programs.* In August 1996, at the request of President Clinton, the Public Health Service agencies jointly co-sponsored a national meeting of state and local officials, researchers, and community experts from the fields of HIV and substance abuse to develop an action plan to more effectively integrate HIV and substance abuse prevention efforts. These agencies are committed to implementing this strategy in the year ahead.

- *Enrolling more substance abusers into drug treatment.* Substance abuse treatment is a major form of HIV prevention. This Administration will continue to press for increased funding for substance abuse treatment. Further, through outreach, research, and demonstration programs, SAMHSA, NIH, and CDC will work to enroll more people in treatment and to find more successful interventions to accomplish this end.
- *Reducing the availability of illegal drugs.* The White House Office of National Drug Control Policy (ONDCP) is leading this fight on two fronts: reducing demand for drugs through treatment and prevention programs and reducing the availability of drugs through supply reduction programs.
- *Preventing HIV transmission from the use of contaminated injection equipment.* The sharing of needles and syringes among injecting drug users is a major means of HIV transmission in the drug-injecting population. While abstinence from drug use is always the preferred means of prevention, the CDC has issued guidelines regarding the use of bleach to clean injection equipment. In addition, CDC-supported research has indicated that removal of restrictions on over-the-counter sale of syringes resulted in decreased reported needle sharing.

Current Federal law prohibits the use of Federal funds for needle exchange programs; however, a number of communities across the country have undertaken these programs with local resources. NIH-supported research on existing needle exchange programs is identifying the characteristics that influence program success as an HIV prevention strategy.

*Primary Care.* HIV prevention needs to be better integrated into primary health care. New and promising medical interventions make it critical to improve our approach to HIV counseling and testing -- creating a critical bridge between prevention and primary care. CDC is committed to improving the return rate of those tested at publicly-funded sites and the quality of referral to services for those who test positive.

The linkage must also go in the opposite direction: from primary care to prevention. Primary care providers must learn to incorporate a person's sexual and drug-using history when a medical history is taken, offering HIV-related counseling and voluntary testing, and providing prevention education to HIV positive individuals as part of the provider-patient relationship. HRSA's AIDS Education and Training Centers (AETCs) have played a crucial role in giving health care professionals the information and skills they need. The Administration strongly supports the AETC program and will give it a renewed focus to support this goal.

Often primary care is a direct form of HIV prevention. The NIH-supported research that showed AZT reduces perinatal transmission of HIV was a tremendous medical breakthrough. Realizing the promise of this advance requires a commitment to assuring that all pregnant women are counseled and offered HIV testing -- and that AZT treatment is available for all who desire it. All Federally-funded programs reaching pregnant women -- from Medicaid to Ryan White CARE Act grantees to community and migrant health centers -- are required to take part in this effort. We are committed to expanding outreach and assuring appropriate care so that the Congressionally-set goal of reducing perinatal transmission by 50 percent by the year 2000 is achieved.

**Other STDs and TB.** Recent research has confirmed that treatment of sexually transmitted diseases (STDs) other than HIV can reduce the likelihood of HIV transmission -- making the need for collaboration between HIV and STD prevention efforts more compelling. In addition, people living with HIV are at very high risk for developing active tuberculosis. Studies suggest that the risk of developing active TB is 7 to 10 percent per year for persons who are infected with both TB and HIV, as opposed to a 10 percent lifetime risk for persons not infected with HIV.<sup>7</sup>

To address the need to integrate work on these interrelated epidemics, CDC organized the new National Center for HIV, STD, and TB Prevention. CDC has initiated -- and will aggressively pursue --

efforts to increase collaboration among these programs, including expanding the community planning program to cover STD programs.

#### ■ ***Targeting Vulnerable Populations***

The HIV epidemic continues to have a disproportionate impact on certain populations where infection rates are rising at a rapid pace. A fifth and final challenge for prevention programming is to pay particular attention to groups that traditionally receive fewer services, but where the risk of infection is greatest. These include adolescents (especially young gay men), women, minorities, gay men of color, substance abusers, and prisoners. Many Federally-funded HIV prevention activities already target these populations, but the President's increased funding request for CDC would provide \$35 million in new funds in FY 1997, specifically for programs and research targeting adolescents, women, and substance abusers. To ensure that prevention programs, including community planning efforts, are as effective as possible all Federally-funded prevention activities routinely will include monitoring and evaluation components.

## **B. RESEARCH**

*"Our common goal must ultimately be a cure, a cure for all those who are living with HIV, and a vaccine to protect us from the virus."*

**President Clinton, December 5, 1996  
The White House Conference on  
HIV and AIDS**

### ***Record of Accomplishment***

Since 1981, the nation has made significant advances in HIV-related research including:

- Identification of HIV as the etiologic agent for AIDS;
- Development of a reliable test to determine exposure to HIV;
- Determination by NIH of the three-dimensional structure of reverse transcriptase, providing the target for the use of AZT as the first antiretroviral drug proven effective against HIV in NIH-supported clinical trials;
- Approval of AZT, the first treatment of HIV primary infection;
- Development by the Food and Drug Administration (FDA) of a system of expedited review,<sup>8</sup> initiated in 1992, of treatments for life-threatening diseases, including HIV; and

Since he took office in 1993, President

Clinton has escalated AIDS research efforts by:

- Increasing AIDS research funding at NIH by 40 percent (since FY 1993);
- Signing the NIH Revitalization Act of 1993, granting the Office of AIDS Research at NIH new authority to develop and implement an annual AIDS research plan and budget;
- Accelerating AIDS drug approval to record times;
- Approval by the FDA since January 1993 of 16 new HIV-related drugs, 8 new indications, and three new diagnostics for HIV and related conditions, developed through public and private sector development efforts;
- Supporting research that led to finding that use of AZT during pregnancy, childbirth, and the first six weeks of life can reduce the transmission of HIV from mother to child by two-thirds;
- Approving in record time a promising new class of AIDS drugs known as protease inhibitors;
- Launching a four-year, \$100 million research effort to develop effective topical microbicides;
- Developing the first Federal Plan for Biomedical Research on HIV and

AIDS to improve coordination of HIV-related research; and

- Facilitating creation of the Forum for Collaborative HIV Research to identify opportunities for clinical effectiveness research to improve care for HIV-positive individuals.

### ***Contributions of AIDS Research to Research on Other Diseases***

AIDS research has provided significant benefits in the fight against many other diseases. AIDS research has accelerated study of the human immune system, helping to better understand and treat such diseases as cancer; autoimmune diseases, including systemic lupus erythematosus; type I diabetes mellitus; rheumatoid arthritis; and multiple sclerosis. AIDS research advances also have contributed to the prevention and treatment of other infectious diseases and provided a new paradigm for treatment of viral diseases.

Progress in the treatment and prevention of HIV-related opportunistic infections has had an enormous impact on the care of patients with other immunodeficiency conditions who are susceptible to many of the same pathogens. This research effort has enhanced the care of cancer patients, patients who have received immunosuppressive therapy for transplants, and the treatment of diseases caused by elevated immune responses (e.g., allergies and lupus).

HIV research has assisted in identifying new infectious agents that may be responsible for malignancies, such as the recent discovery of the etiologic agent for Kaposi's sarcoma. These findings may help to identify other oncogenic agents. HIV research has led to a better understanding of the mechanisms by which infectious agents and inflammatory cells cross the blood/brain barrier, providing valuable clues for research on Alzheimer's disease, dementia, multiple sclerosis, neuropsychological disorders, encephalitis, and meningitis. Studies to develop anti-HIV therapies have improved our understanding of additional viral diseases and led to development of treatments.

Efforts to develop drugs for the treatment of HIV have accelerated the development of methods of targeted drug design using sophisticated techniques of structural biology and advanced computer imaging methods. These advances have implications for drug design for virtually all disorders. Clinical trials of poxvirus vaccine vectors and adjuvants in HIV vaccine candidates have supported safety information for cancer vaccines. Research on HIV-related wasting has provided important information for research on nutritional disorders, metabolic abnormalities, and gastrointestinal dysfunctions.

### ***Future Opportunities for Progress***

While tremendous progress has been made in HIV research, we cannot and will not diminish our effort until we have found a cure and a preventive vaccine. To accomplish this national goal, we must

address four ongoing challenges:

- Provide leadership and coordination for the Federal research effort;
- Develop biomedical interventions that prevent HIV infection, including both vaccines and microbicides;
- Develop new and more effective therapies for HIV and related conditions; and
- Assure adequate funding for this research effort.

■ *Leadership and Coordination of Research*

Developing and implementing the Federal government's AIDS research agenda presents both scientific and logistical challenges that require leadership, coordination, and strategic planning, first among the 24 institutes, centers, and divisions of the NIH, and second among the various Departments and Agencies throughout the government that support HIV research.

The strengthened authority and new leadership of the NIH Office of AIDS Research and the first Federal Biomedical and Behavioral Research Plan and Budget for HIV and AIDS form the basis for better coordination of our research effort and provide the assurance that key questions are being answered systematically and without duplication. Over the next year, the Clinton

Administration is committed to the reauthorization of the OAR's authority and assuring that its budget powers are maintained throughout the appropriations process.

As part of the ongoing commitment to assess all aspects of our research effort, the OAR convened a panel of outside experts to evaluate NIH's AIDS research programs. The Report of the NIH AIDS Research Program Evaluation Task Force included several key recommendations that will be implemented in the year ahead. These include:

- Increase NIH support for basic science through investigator-initiated research;
- Establish a restructured trans-NIH vaccine research effort;
- Augment research efforts to better understand the human immune system;
- Develop a comprehensive NIH HIV prevention science agenda, combining biomedical, behavioral, and social interventions; and,
- Improve coordination among all NIH-supported AIDS clinical trials programs.

■ ***Biomedical Prevention of HIV Infection***

***Vaccine Development.*** The scientific community continues to strive for an effective vaccine against HIV infection. The Federal government, through the NIH and the Department of Defense, will continue to support two approaches to vaccine development. The first approach is based on the belief that gathering additional basic science information offers the best hope in steering vaccine development and that many critical questions must be answered before human trials should begin. The second approach is guided by the belief that data gathered from clinical efficacy trials of vaccine candidates in humans can lead to the development of a successful candidate and that if a safe candidate is available, it is not necessary to resolve all of the scientific questions before proceeding with human trials. Both approaches will continue to be pursued on a parallel and interrelated path. Small trials of more complex vaccine products and two types of vaccine candidates have been underway for several years, and larger trials are planned for the near future.

***Microbicides.*** Many scientists believe that in the absence of a vaccine the development of safe and effective mechanical or chemical barrier methods that will block HIV transmission or prevent other sexually transmitted infections could dramatically reduce the sexual transmission of HIV. Worldwide, more than 80 percent of HIV infections are acquired heterosexually and women are more easily infected than men. Moreover, the risk of becoming infected or

infecting others is substantially increased by the presence of other STDs.<sup>9</sup>

Latex condoms, the most effective barrier methods currently available, still have limitations. Most require the consent, if not the active participation, of both partners and therefore cannot be independently used at the discretion of one partner. An easily available and inexpensive microbicide could provide a prevention option for millions of people worldwide.

To address these goals, the following steps will be taken:

- During FY 1997, NIH and CDC will begin to implement a four-year, \$100 million initiative on microbicides announced by HHS Secretary Shalala at the Eleventh International Conference on AIDS;
- The Vice President will continue a high-level dialogue designed to encourage private sector involvement in the development of both microbicides and vaccines; and,
- Through U.S. participation in UNAIDS, and in other forums, we will encourage international efforts to develop effective microbicides.

■ ***Developing New and More Effective Therapies***

Another challenge in the research arena is developing new and more effective therapies

that may allow us to transform HIV disease into a chronic manageable condition. While the FDA is approving new treatments in record numbers and at record speed, the long-term clinical effectiveness of these new therapies remains unknown. There is no doubt that new drugs must be developed.

To accomplish this, NIH will spend an estimated \$470 million in the area of therapeutic research in FY 1997. In addition, several other initiatives will be undertaken or maintained:

- *Federal support for the Forum for Collaborative HIV Research will promote public-private collaboration in AIDS research.* This new group, formed at the behest of Vice President Gore, is designed to catalyze collaborations among the government research establishment, pharmaceutical companies, and third-party payers to capitalize on recent scientific advances and learn how to optimally use available treatment regimens. The Federal government is committed to being an equal partner in this new effort.
- *A Federal commitment to continued access to sophisticated equipment and personnel that can be shared among researchers in both the private and public sectors.* The Department of Energy (DOE) has made available the use of sophisticated imaging equipment that would otherwise be prohibitively expensive for individual researchers

or companies. This shared resource has accelerated the understanding of molecular structures in a number of research fields, including HIV. Information gained from this research can form the basis for targeted drug design and development.

- *Increased focus in Federal research on vulnerable populations.* Our research effort will increase its focus on the needs of vulnerable populations, including youth, women, minorities, and substance abusers. The efforts of programs such as the Women's Interagency HIV Study (WIHS), the Terry Bein Community Programs for Clinical Research on AIDS (CPCRA), and the Adolescent Medicine HIV/AIDS Research Network are important to improving our understanding of HIV disease in these populations and will continue.

■ *Continued Support for Research*

HIV research is an investment in our future. Already, it has helped prolong and improve the quality of lives of HIV-infected individuals, and we must continue to make this investment. To unleash the talents of the best and the brightest in finding a cure, better therapies, and a vaccine will require a sustained funding commitment to meet the research challenges. NIH currently receives many more outstanding research applications than it is able to fund -- representing a lost

opportunity for scientific progress. Other Agencies, such as DOD, CDC, and VA, also support crucially important HIV research that strengthens the overall U.S. research effort. Recognizing the importance of biomedical and AIDS research generally, for FY 1997, the President has requested an increase of \$449 million for the NIH overall, an increase of \$24 million for NIH-conducted and -supported AIDS research, and an increase of \$4 million for AIDS research government-wide.

## **C. CARE & SERVICES**

*"AIDS has taken too many friends and relatives and loved ones from everyone of us in this room. It has shaken the faith of many, but it has inspired a remarkable community spirit."*

**President Clinton, May 20, 1996  
Signing of the Ryan White  
CARE Act Reauthorization**

### ***Record of Accomplishment***

Since the epidemic of HIV and AIDS began in 1981, more than 500,000 Americans have been diagnosed with AIDS and required care. As the number of Americans living with AIDS increased, the demands on the U.S. health care system increased dramatically, but Federal, State, and local governments along with community-based organizations and private clinicians have responded with compassionate, high-quality medical care. In 1986, Federal expenditures for HIV-related care and services were \$193 million, by 1995 the Federal share reached \$3.5 billion.

In the early years of the epidemic, the health care infrastructure was particularly unprepared to accommodate the health care needs of persons with HIV. To meet their complex health care needs, HIV-positive persons were often forced to negotiate a fragmented system of care. There were few programs designed to meet the unique care needs of HIV-positive individuals. Moreover, available care services were often directed towards meeting the acute care

needs of persons diagnosed with AIDS, rather than intervening in the early stages of HIV disease. While we still have far to go, the quality and availability of services for HIV-positive persons has improved significantly.

People living with HIV now access and finance health care services in a variety of ways. Currently, approximately 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.<sup>10</sup>

In addition to Medicaid, the centerpiece of the national safety net for HIV positive people is the programs funded through the Ryan White Comprehensive AIDS Resources Emergency (CARE) Act of 1990, administered by the Health Resources and Services Administration (HRSA). The CARE Act programs were established to fill gaps in coverage and build systems of care to create access to health care for people living with HIV and AIDS. The first four titles of the CARE Act support direct services for people living with HIV:

- 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. Title II also provides drug

reimbursement funding for persons living with HIV/AIDS under the AIDS Drug Assistance Program (ADAP).

- Title IIIb of the CARE Act provides early intervention services such as counseling and testing, medical care, and educational services for medically underserved persons with the goal of reducing HIV-related illness.
- Title IV seeks to increase the availability of research, care and services for women, infants, children, and youth in a community-based family-centered system of care.
- Title V provides reimbursement for dental care for low income persons living with HIV and AIDS and supports AIDS Education and Training Centers which provide up-to-date HIV-related training for health care professionals.

HRSA also provides primary care to persons living with HIV through its Community Health Centers and Maternal and Child Health Block Grant 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 (IHS), which provides health care for HIV-positive Native Americans and Alaska Natives. Additionally, the Bureau of Prisons within the Department of Justice

provides care for HIV-positive people in Federal prisons.

People living with HIV and their families face significant obstacles to locating affordable housing. Housing assistance for people living with HIV and AIDS is provided by the Department of Housing and Urban Development (HUD) through its Housing Opportunities for Persons with AIDS (HOPWA), enacted in 1990, and other programs, such as the Section 811 Supportive Housing Programs for Persons with Disabilities. These programs work in partnership with local initiatives incorporating housing assistance into a community's continuum of services.

To further foster community involvement, HUD also has 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. The Community Development Block Grant (CDBG), the HOME affordable housing program, as well as public housing programs are key resources that are available to communities.

Since he took office in 1993, President Clinton has built on this record by making AIDS a top national priority and increasing that national commitment by:

- Increasing funding for the Ryan White CARE Act by 158 percent since FY 1993 and signing the Ryan White CARE Act Amendments of

1996, extending this program until 2001;

- Tripling Federal funding for State AIDS Drug Assistance Programs, which help uninsured and underinsured individuals purchase prescription drugs;
- Increasing funding for HOPWA by 96 percent since FY 1993;
- Winning the fight to preserve the Medicaid guarantee of coverage for the more than 50 percent of people with AIDS and 90 percent of children with AIDS who rely on this program for their health coverage; and,
- Revising eligibility rules for Social Security disability benefits to make it easier for people living with HIV to qualify for benefits.

### ***Future Opportunities for Progress***

The national goal in this area is to ensure that people living with HIV have the opportunity to live productive lives by having access to services that are affordable, of high quality, and responsive to their needs. AIDS care and service programs must continue to provide access to care for those without insurance coverage, improve prioritization and accountability, and increase the cost-effectiveness of services they provide. As treatments improve and extend the productive lives of people with

HIV, we must continually reexamine the range of services that are needed.

Two major challenges exist in meeting this goal:

- Maintaining HIV-related care and services as an investment priority in budgeting in the context of a balanced Federal budget: fighting to preserve Medicaid and continuing to seek funding for CARE Act and HOPWA programs.
  - Assuring that available resources are used as effectively as possible.
- ***Making Investment in Care and Services a Budget Priority***

***Preserving Medicaid.*** As the epidemic continues to spread in lower-income communities, Medicaid will be an even more essential lifeline of support for Americans living with HIV and AIDS. The need to maintain the historic Federal-State partnership on Medicaid has never been greater. Proposals in Congress to convert Medicaid into a block grant would endanger access to care for people living with HIV and AIDS, particularly proposals to eliminate or weaken the Federal guarantee of coverage for people living with disabilities. The President has vetoed one such proposal and has made sustaining the entitlement to Medicaid central to the national goal of ensuring appropriate and affordable care and services for persons living with HIV and AIDS.

**Assessing Social Security Administration Programs.** With the improved quality of life realized by many people due to the advent of protease inhibitors and combination therapy, it is important to assess programs such as Supplemental Security Income and Social Security Disability Insurance regarding their flexibility in meeting the needs of individuals as they seek to move off and on to disability. The current system of disability programs, which assures continued access to health insurance, often places obstacles in the way of individuals who want to return to work. The Administration is exploring mechanisms to ensure that Federal programs support people with disabilities who want to work or return to work.

**Continuing Support for the Ryan White CARE Act.** The five-year reauthorization of the CARE Act signed by President Clinton on May 20, 1996 provides people living with HIV and AIDS with peace of mind that support from the Federal government will continue. President Clinton has proposed \$896 million for this program in FY 1997.

**Expanding Support for Housing Services.** Finally, maintaining consistent funding for the housing component of the services safety net will continue to be a national priority. Without stable housing a person living with HIV has diminished access to care and services and a diminished opportunity to live a productive life. It is estimated that up to 50 percent of people living with HIV and AIDS are or will be at risk of becoming homeless during the course of their illness.<sup>11</sup> The President's FY 1997

amended budget request for HOPWA is \$196 million.

■ ***Ensuring Effective Use of Limited Resources***

There are three primary ways the Federal government will work to make the most of its limited resources by: (1) improving coordination among Federal programs, (2) improving the quality of care provided by those programs, and (3) evaluating program effectiveness to ensure that funds are well spent.

**Improving Program Coordination.** Integrating HIV and related services is an important step in assisting communities to build seamless systems of support for our most vulnerable citizens. Organizations receiving Federal funding to provide AIDS-related care often require support from several Federal agencies. For example, creating a comprehensive community-based program that integrates primary care, substance abuse treatment and prevention, sexually transmitted disease screening, HIV prevention, access to clinical trials, and housing assistance requires separate applications to SAMHSA, HRSA, CDC, NIH, and HUD.

The agencies funding HIV-related services are committed to simplifying and improving the application process for Federal funding and to facilitating service integration. HRSA and SAMHSA have issued joint program announcements, and HUD and HRSA have issued a joint program announcement for the Special Projects of

National Significance (SPNS) program. These concerted efforts to improve integration will be continued and expanded, with special attention to linking HIV and substance abuse prevention and services.

***Improving Quality of Care.*** Federally-supported efforts such as Medicaid, Medicare, and the health care delivery systems at the Department of Veterans Affairs (VA) and the Department of Defense (DOD) can and should consistently provide high-quality care. Ensuring consistency in care delivery requires increased training for health care professionals and greater accountability through the use of performance measures for quality care. It is also essential that practical information on research advances for practicing clinicians and their patients be provided in a timely manner. (See Section Translation of Research Advances in Practice.) HRSA and HCFA will continue to offer guidance to grantees and the States regarding maintaining the quality and standard of care appropriate for people living with HIV. To this end, during FY 1997, the Office of HIV/AIDS Policy at HHS is undertaking a program to develop clinical practice guidelines in conjunction with other government Agencies such as the VA and DOD and private-sector clinicians.

***Evaluating Program Effectiveness.*** Strong Federal support for safety net programs must be accompanied by improved accountability and priority setting. Evaluating current activities provides valuable information for planners and those at the front lines of the epidemic and assists

in providing better care to people living with HIV.

## **D. CIVIL RIGHTS**

*"Every person with HIV or AIDS is someone's son or daughter, brother or sister, parent or grandparent. We cannot allow discrimination of any kind to blind us to what we must do."*

**President Clinton, May 20, 1996  
Signing of the Ryan White  
CARE Act Reauthorization**

Discrimination against people living with HIV or AIDS violates the human rights of individual Americans and undermines our efforts to prevent and treat HIV infection. The extraordinary stigma that has been attached to HIV disease hampers the ability of people living with HIV and AIDS to live full lives free of fear.

Discrimination also undermines efforts to prevent and treat HIV infection and bring the epidemic under control. Fear of discrimination and stigma causes many people not to seek testing for HIV; thus many remain unaware of their HIV status and go without the care that could help them live longer, healthier lives. Opportunities to educate people are also lost as people avoid prevention programs because of the stigma associated with HIV.

The fourth goal of the National AIDS Strategy is to fight discrimination on all fronts, including employment, access to health care, education, housing, service establishments, and other areas covered by Federal law, and to provide national

leadership in erasing the stigma associated with HIV and AIDS.

### **Record of Accomplishment**

During the early years of the AIDS epidemic, protection of the civil rights of people living with HIV and AIDS was sporadic, at best. Individual lawsuits were the first line of action. By the late 1980s, however, the Federal government began to respond more aggressively with actions including:

- Enactment of the Harkin-Humphrey Amendment to the Civil Rights Restoration Act, clarifying that Section 504 of the Rehabilitation Act of 1973 applied to people with contagious diseases, including HIV; and
- Enactment of the Americans with Disabilities Act of 1990 (ADA), which protects individuals living with HIV and AIDS and people perceived to be at risk for HIV from discrimination in housing, employment, and public accommodation.

Since he took office, President Clinton has directed relevant Agencies to make enforcement of the civil rights of people living with HIV and AIDS a priority. Key actions include:

- Vigorously enforcing the ADA by the Justice Department, the Equal

Employment Opportunities Commission, and the Department of Health and Human Services;

- Vigorously enforcing Section 504 of the Rehabilitation Act of 1973 as it pertains to recipients of Federal funds such as hospitals, nursing homes, and social service agencies;
- Leading the effort to repeal the "Dornan Amendment," which would have required the discharge of all military personnel who are living with HIV. President Clinton declared the proposal unconstitutional and directed the Department of Justice not to defend it if challenged in court;
- Establishing an HIV/AIDS education program available to all Federal workers; and
- Using the Presidential "bully pulpit" to speak out repeatedly against discrimination against people with HIV and AIDS. In December 1995, the President hosted the first ever White House Conference on HIV and AIDS, bringing to the White House more than 300 people from around the country to discuss with the President the impact of the epidemic on their lives and communities.

### *Future Opportunities for Progress*

There are four key ways that the Federal government is maintaining its commitment to meeting the goal of ensuring that people living with HIV are not subject to discrimination:

**Enforcing Rights.** Efforts to protect the civil rights of people with HIV and AIDS must be ever-vigilant. The Federal government will continue to exhibit strong leadership on this issue through its enforcement of the Americans with Disabilities Act and public condemnation of discriminatory acts or statements. Of particular concern is discrimination against people with HIV seeking access to health care and health care facilities. A joint effort by the Department of Health and Human Services and the Department of Justice aimed at access to nursing homes is a significant step forward in protecting the rights of people living with HIV.

**Protecting Workers.** The Federal government is examining existing policies related to the exclusion of people living with HIV from Federal employment. The Director of the Office of National AIDS Policy is working with Federal Agencies to examine individual policies to determine whether they comply with Federal public health guidelines.

**Opposing Discriminatory Legislation.** The Administration will continue to oppose, in the strongest terms possible, efforts by the Congress to discriminate against people living with HIV and AIDS.

**Providing Leadership.** Leaders of

government have an obligation to use the power of their elected office to speak out against acts or words of discrimination against any group of people. President Clinton and members of his Administration have used and will continue to use their positions to oppose discrimination against people living with HIV and AIDS.

## **E. INTERNATIONAL ACTIVITIES**

*"The American people need to know that everybody in this country and, indeed, throughout the world, is now vulnerable to this disease."*

**President Clinton, December 5, 1996  
The White House Conference on  
HIV and AIDS**

AIDS is a global epidemic. The World Health Organization (WHO) estimates that 94 percent of new infections occur in developing countries. In the United States it is estimated that between 650,000 and 900,000 people are currently infected with HIV. The WHO and UNAIDS estimates that 27.9 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 by the year 2000. Two to three million new HIV infections can be expected annually, and by the year 2000, 30 to 40 million people will have been infected around the globe.

The epidemic jeopardizes decades of economic and social advances in many developing nations. In some of the nations of Africa and Asia, economic advances are threatened and in some cases may be reversed due to HIV and AIDS. Socio-economic studies have shown a decrease in overall domestic savings and investment levels, negative effects on foreign investments, reductions in the volumes of imports and exports, and a reduction in receipts from tourism.<sup>12</sup> In many countries governments will be forced to cope with increasing numbers of cases, weakened

health care systems, a deleterious economic impact on the most productive segments of society, and the reduction in the number of healthy men and women able to serve in the government and the military.

### ***Record of Accomplishment***

Since it began, HIV and AIDS has been a global concern. The U.S. has worked closely with developed and developing nations to design an international response that is both vigorous and coordinated. Sentinel achievements include:

- Providing initial funding and key leadership for the creation of the Global Programme on AIDS at the World Health Organization (WHO) in 1987; and
- Playing an instrumental role in establishing the new streamlined Joint United Nations Programme on HIV/AIDS (UNAIDS) in 1996.

The United States is the largest contributor to international efforts to combat the pandemic of HIV and AIDS. Several Federal Agencies are working to slow the AIDS epidemic internationally. (See Appendix E). The Department of State works with other Agencies and non-governmental organizations to implement a framework to guide U.S. foreign policy in the global efforts against HIV and AIDS. The major areas of U.S. leadership in the global HIV arena are: mobilizing and unifying national and international efforts; preventing new infections; biomedical

research; and reducing the personal and social impact of the epidemic.

The U.S. Agency for International Development (USAID) plays a leadership role in the global HIV response through development assistance, research, and policy formulation. USAID focuses its efforts on developing prevention programs based on proven interventions; addressing social, cultural, regulatory, and economic issues related to HIV and 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 Peace Corps trains a portion of its volunteers to directly address HIV-related concerns in their countries of placement. The U.S. Information Agency (USIA) supports programs that promote dissemination of U.S. policies and information related to HIV and AIDS.

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. The DOD is conducting clinical trials of candidate HIV vaccines in Thailand and NIH (working in collaboration with USAID), supports a range of scientific studies in developing countries. The results of the studies ultimately will be used to develop interventions to reduce behaviors that place individuals at risk for contracting HIV infection.

### ***Future Opportunities for Progress***

To accomplish the goal of providing strong

continuing support for international efforts to address the HIV epidemic, the following steps will be taken:

***International Leadership.*** The United States has established a global leadership role in combatting the epidemic. This leadership will continue. The U.S. strongly supports the newly established Joint United Nations Programme on HIV/AIDS (UNAIDS).<sup>13</sup> The U.S. is a member of the governing body of UNAIDS, signed the 1994 Paris Declaration, and also supports the Greater Involvement of People Living with HIV and AIDS Initiative (GIPA).

The U.S. also supports efforts to access available resources more effectively as well as encourage non-traditional donor countries to provide much-needed contributions. Supporting UNAIDS organizations such as UNICEF, WHO, UNDP (United Nations Development Program), the U.S.-Japan Common Agenda and its innovative programmatic efforts, and UNAIDS' 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.

***Strengthening Partnerships.*** In addition to maintaining multilateral partnerships, the U.S. must strengthen its bilateral programs for HIV activities and continue to support developing countries where more than 90 percent of the world's AIDS cases are found.

***Sharing Technology and Bringing Lessons Home.*** Through USAID's "Lessons Without Borders Project," the U.S. has gained valuable insights from experiences in participating countries and is applying them to communities here at home. The initiative brings lessons learned abroad back to inner-city and rural areas with problems similar to those experienced overseas. These efforts will be continued and expanded for HIV and AIDS.

***Improving 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. In order to ensure that efforts are productive, the U.S. Agencies supporting international activities must develop a mechanism for coordinating programs in a systematic and efficient manner.

## **F. TRANSLATION OF RESEARCH ADVANCES INTO PRACTICE**

*"I want all our fellow Americans to know that this investment in science has paid tremendous dividends."*

**President Clinton, December 5, 1996  
The White House Conference on  
HIV and AIDS**

An important element in the fight against HIV and AIDS is ensuring that research advances are translated into improved HIV prevention programs and better care for HIV-positive persons. While directly related to earlier goals relating to research, prevention, and care and services, it is important to highlight this aspect of the nation's response to the epidemic to assure that we are taking what we are learning and translating it into benefit for people with or at risk for HIV.

An example of the importance of such efforts is the translation of the NIH-supported research study that found that the use of AZT by pregnant women during pregnancy and childbirth and its application to newborns for the first six weeks of life can reduce the risk of perinatal transmission of HIV by two-thirds. Translation of these results required actions by the National Institutes of Health and the Centers for Disease Control and Prevention, which prepared guidelines for physicians caring for pregnant women and for consumers; the Health Resources and Services Administration, which provided guidance to grantees on coverage of such services; the

Health Care Financing Administration, which provided similar guidance to State Medicaid Directors.

### ***Record of Accomplishment***

Due in part to Federally-sponsored information dissemination activities, dramatic changes in the way HIV is treated have taken place. Ensuring dissemination of HIV-related information falls under the missions of several Agencies (See Appendix F). Key examples are:

- 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, patients, the media, and the public;
- DHHS supports and directs the International HIV/AIDS Clinical Conference Call series, which disseminates state-of-the-art clinical care information to primary care providers via live worldwide audio tele-conferencing;
- NIH supports publicly available computerized databases such as AIDSDRUGS, AIDSTRIALS, and AIDSLINE;
- The toll-free 1-800 TRIALS-A AIDS Clinical Trials Information Service (ACTIS) is co-sponsored by NIH, CDC, and FDA;

- The Centers for Disease Control and Prevention disseminates information to clinicians, patients, and the public through the National AIDS Hotline (1-800-342-AIDS); its toll-free 1-800-HIV-0440 HIV/AIDS Treatment Information Service (ATIS); and the National AIDS Information Clearinghouse;
- The CDC also develops and issues guidelines for health professionals and the public through its *Morbidity and Mortality Weekly Report*;
- The Agency for Health Care Policy and Research (AHCPR) publishes a series of HIV-related clinical practice guidelines for clinicians and companion pamphlets for their patients; and,
- The Health Resources and Services Administration directs a nationwide system of AIDS Education and Training Centers that provide state-of-the-art HIV clinical information to health care providers. HRSA also has developed guidances for its Ryan White CARE Act grantees and funds an AIDS "warmline" that responds to questions from clinicians across the country.

### ***Future Opportunities for Progress***

Ensuring that research advances are translated into improved HIV prevention programs and better care for HIV positive

persons, will require a number of steps including:

***Increasing Education and Training.*** As we continue to expand our base of knowledge about AIDS care, efforts to educate and train health care professionals in state-of-the-art care for people living with HIV and AIDS must be maintained. An AHCPR-supported study indicated that primary care physicians may miss significant HIV-related symptoms during patient examinations.<sup>14</sup> Other research indicates that a disturbing number of clinicians do not use universal precautions in the course of routine patient care.<sup>15</sup> To reverse this pattern, the Administration is fighting to restore funding for the AIDS Education and Training Centers, which play a vital role in training providers. Achieving this goal will also require a renewed emphasis on HIV on the part of medical schools, professional organizations, and individual clinicians.

Consumer education efforts are also important. In light of the potential public health benefits that could result from the proper use of a wide range of therapies, it is vital to support programs that provide consumers with the information they need to make treatment decisions and comply with therapeutic regimens.

***Disseminating 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 for their patients. With every research breakthrough, this task becomes more difficult. It is

essential that practical information for practicing clinicians and their patients be provided as quickly as possible. To this end, during FY 1997, the Office of HIV/AIDS Policy at HHS is undertaking a program to develop clinical practice guidelines in conjunction with other government Agencies and private sector clinicians.

make a difference.

***Improving Coordination of Federal Activities.*** Enhancing coordination of information dissemination activities among Public Health Service Agencies is an important priority. Within DHHS, the Office of HIV/AIDS Policy (OHAP) 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 people and organizations, and that policies and standard-of-care practices for Federally-sponsored programs are modified to reflect the latest treatment developments, requires a continued high level of cooperation and coordination among Public Health Service Agencies.

***Disseminating Prevention Models.*** Improved dissemination efforts also are needed in the area of primary prevention models. Models of effective prevention interventions have been developed, but often this valuable information is not reaching those people developing, implementing, and evaluating prevention programs. The Public Health Service will take the lead in ensuring that information that can be used to stem the tide of new infections reaches those who can

**Endnotes**

1. It is, however, hoped that with greater use of AZT by HIV-positive pregnant women, the number of new cases in newborns can be reduced.
2. *Morbidity and Mortality Weekly Report*. U.S. Department of Health and Human Services, Public Health Service. November 24, 1995, vol. 44, No. 46.
3. Hellinger, F. The Lifetime Cost of Treating a Person with HIV. AHCPR Publication Number 93-0080.
4. For 5 years of care after initial heart attack. Source: *American Journal of Cardiology*, 1990.
5. Depending on stage diagnosed -- early or late. Source: Swartz & Rollins, *Business and Health*, 1985, 85, 24-6.
6. Richard D. Moore and John G. Bartlett. Combination Anti- retroviral Therapy in HIV Infection, An Economic Perspective. *PharmacoEconomics* August 1996; 10(2):109-113.
7. Personal communication from the Centers for Disease Control and Prevention, Division of TB Elimination, 1995.
8. 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.
9. Alan B. Stone, and Penelope J. Hitchcock. Vaginal Microbicides for Preventing the Transmission of HIV. *AIDS* 1994, 8 (suppl 1):S285-S293.
10. Agency for Health Care Policy and Research: Data from the Screener Questionnaire, AIDS Cost and Services Utilization Survey. 1991.
11. Housing and the HIV/AIDS Epidemic: Recommendations for Action. National Commission on AIDS. Washington, D.C. July 1992.

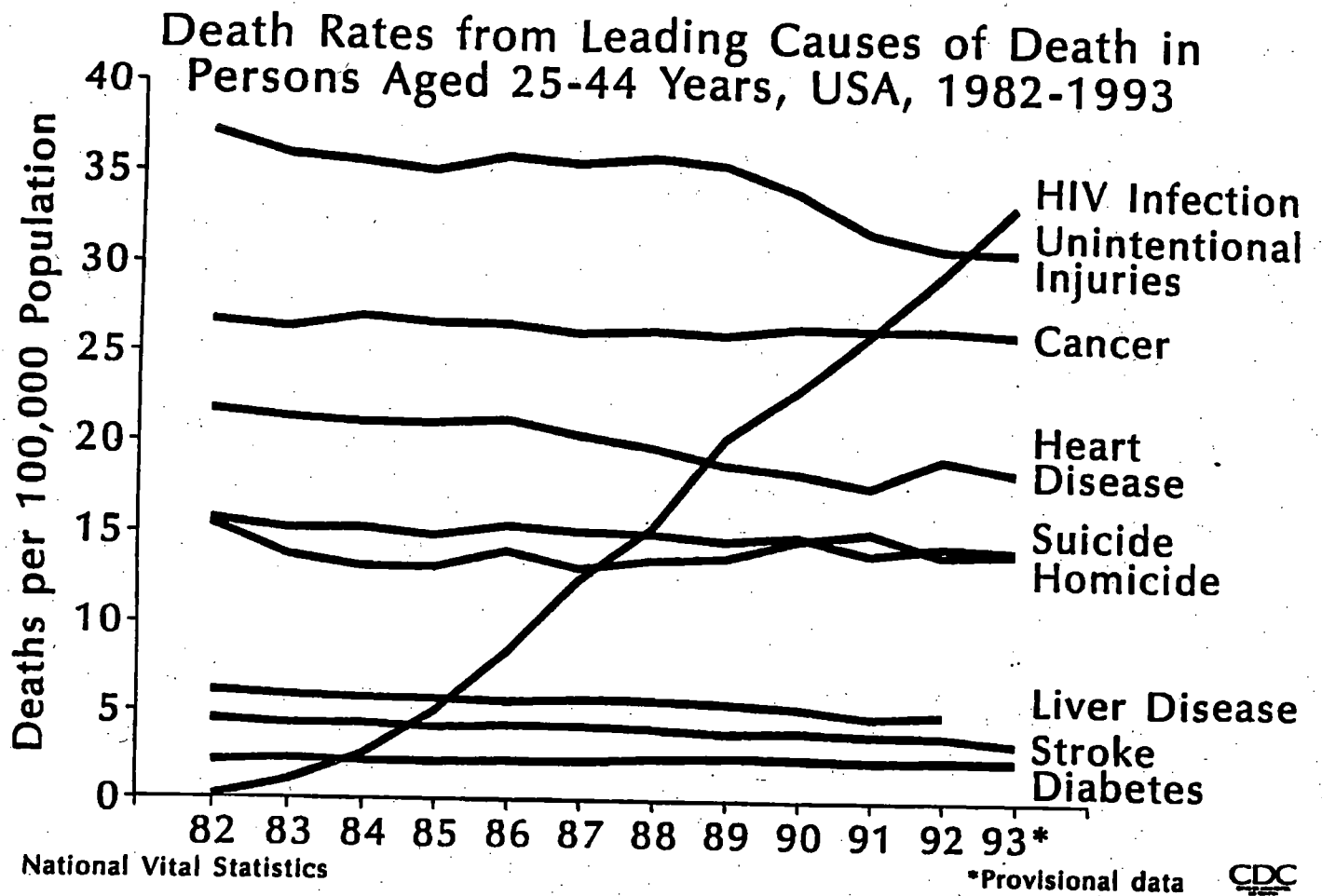
12. *HIV/AIDS Policy Guidance*. U.S. Agency for International Development. September 1995.

13. 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, multi-sectoral responses to the pandemic.

14. 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.

15. 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)

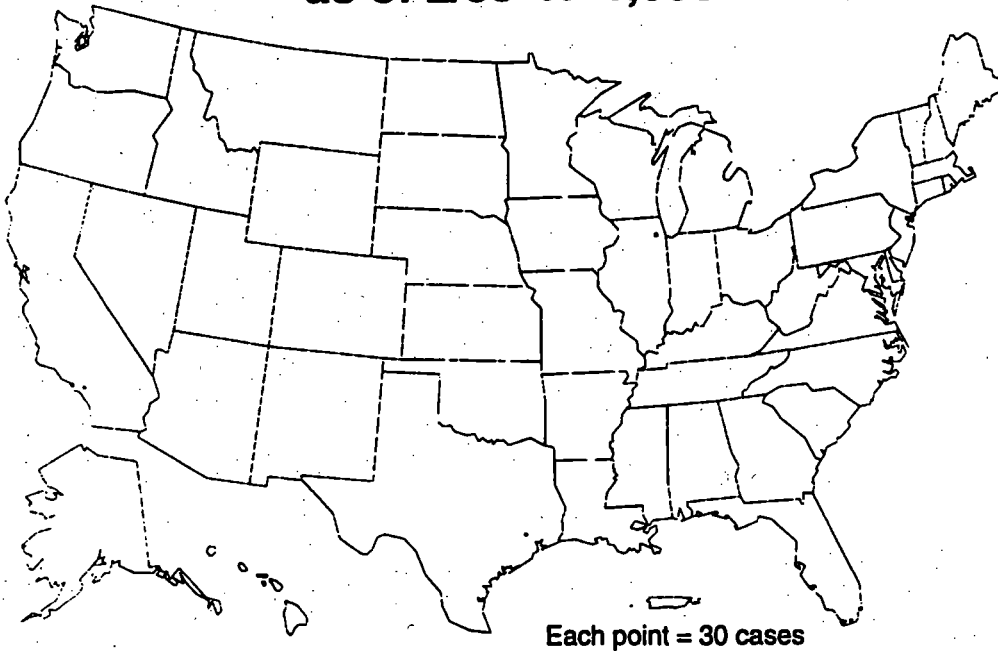
FIGURE 1



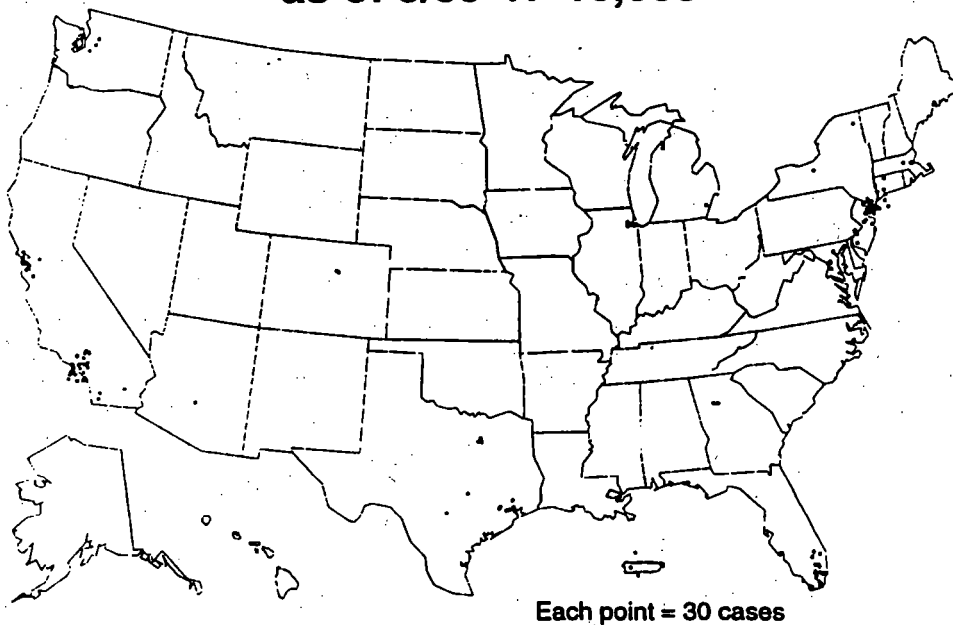
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**FIGURE 2**

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

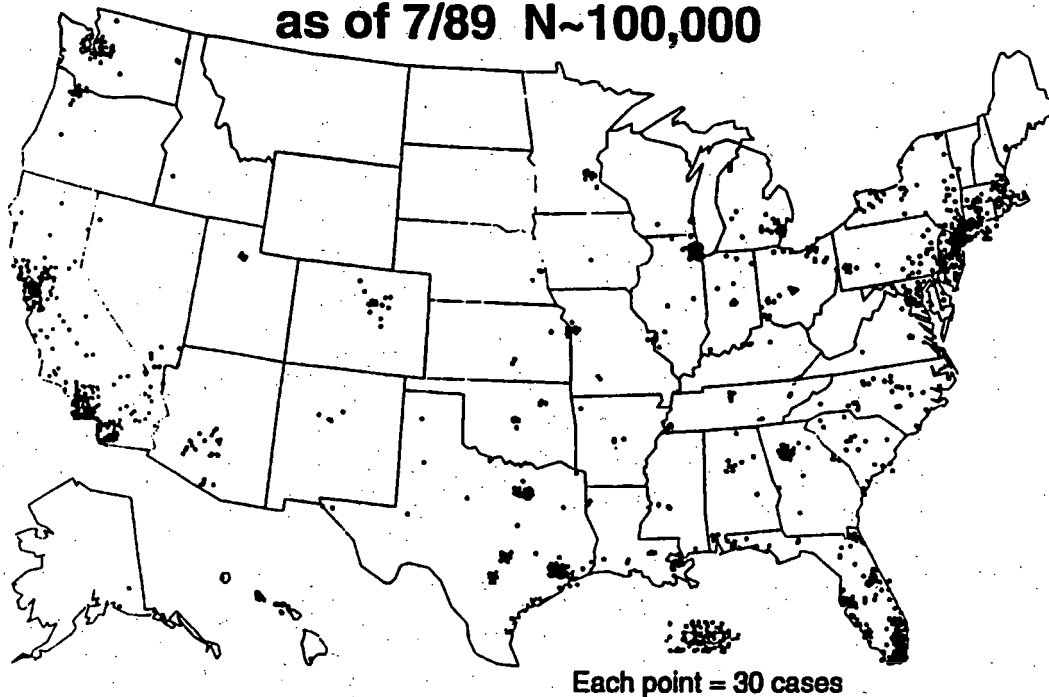


**Cumulative U. S. AIDS Cases  
as of 5/85 N~10,000**



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



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

