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Subseries: National AIDS Strategy

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Comments on National Plan (February 1996 Version that Went to Agencies) [1]

Stack:	Row:	Section:	Shelf:	Position:
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HHS -

OPA
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OIA
SAMSHA

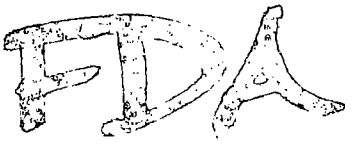
HRSA
HCFA
CDC
NIH

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
Rockville MD 20857

MEMORANDUM



Date: March 6, 1996

To: Patricia S. Fleming
Director, Office of National HIV/AIDS Policy

From: Theresa A. Toigo, RPh, MBA
Associate Commissioner for AIDS and Special Health Issues
Food and Drug Administration

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

Thank you for the opportunity to comment on the draft National Strategy for HIV and AIDS document. We have suggested revised wording for sections of the document which specifically address FDA's activities. These suggested revisions are listed below. In addition, we do not think that this document reflects all of FDA's significant HIV/AIDS prevention and research related activities. Examples of additions to the document you may want to consider include a discussion of the development of new materials for barrier products, evaluation of new types of HIV test kits, expanded access programs for people who can not enroll in controlled clinical trials, and blood safety initiatives. Please let me know if you would like us to submit draft language for any of these subject areas.

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

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Health Resources and
Services Administration
Rockville MD 20857

FEB 23 1996

HRSA

TEXT →
N:\TRISHA\
OUTLIN20.A96

Appendix
N:\TRISHA\HRSA.E96

NOTE TO PATSY FLEMING

SUBJECT: Comments on National Strategies for HIV/AIDS

This is to congratulate you and your office on the development of this important document. I have comments below which I hope will be helpful:

page 9, bullet 3:	should read HIV/AIDS rather than AIDS
page 10, paragraph 2, line 3:	strike "very different" and replace with "increasingly more complex"
page 10, paragraph 3, line 5:	strike "receive quality health care" and replace with "benefit from scientific advances capable of prolonging and increasing quality of their lives."
page 11, paragraph 2, line 6:	strike the word "treatment" (as it stands, it implies that there is no treatment for AIDS.)
page 12, paragraph 1, line 13:	add "academic institutions, private foundations, health care institutions" after "State and local governments" and before "and community based organizations."
page 15, paragraph 1, line 19:	add at end of paragraph this sentence: "HRSA also has undertaken special initiatives designed to reduce perinatal transmission of HIV and has promoted primary prevention through the training of health professionals in the AIDS Education and Training Centers Program.
page 20, paragraph 3:	In addition to alcohol, cocaine use linked with sex-for-drugs is an important factor.
page 20, paragraph 5:	This would be a good place to stress the importance of maintenance of traditional (directly observed therapy) public health approaches to TB surveillance, prevention, and treatment.

Treatment for STD & TB

page 31, paragraph 1:	Insert after the first sentence: "Many Americans are uninsured by either public or private means. Additionally, poverty, racism, homophobia, geography, and other barriers create access problems beyond those related to lack of insurance. These barriers to access are exacerbated in the context of HIV/AIDS. For individuals with health insurance, maintaining adequate coverage...." Strike "For many of these persons, maintaining..."
page 31, paragraph 4, line 5:	strike " to fill certain gaps in coverage for people living with HIV/AIDS." and replace with "fill gaps in coverage and build systems of care to create access to health care for people living with HIV/AIDS."
page 31, paragraph 4, line 11:	IIIb not III
page 32, paragraph 1:	add as a final sentence: "HRSA also supports professional education so that there will be an adequate supply of providers knowledgeable in HIV/AIDS treatment."
page 33, paragraph 2:	rather than "counseling and testing" you might consider using the broader term "primary prevention."
page 35, paragraph 3:	strike "medical schools", add "professional schools"
page 37, paragraph 1:	the importance of activities supporting treatment of STDs, particularly genital ulcer disease, in prevention of transmission of HIV, is extremely important in developing ~~countries~~.
page 38, paragraph 2, line 13:	strike the word "identifying" (identifying what?)
page 39, paragraph 1, line 6:	strike "caring for" replace with "assessing risk, prevention, and caring for"
page 39, paragraph 2, line 22:	strike the last sentence. Replace with, "The Health Resources and Services Administration has developed guidances for its CARE Act grantees, supports international clinical conference calls on current topics, funds an AIDS warmline which responds to questions from clinicians across the country, and directs a nationwide system of AIDS Education and Training Centers which provide State

Prevention
HIV/STD, TB

of the art HIV clinical information to health care providers. Additionally, HRSA supports a number of conferences featuring clinical updates and information."

Opportunities for Progress p. 41

page 40, paragraph 2, line 3: strike phrase, "study indicated that primary care physicians miss..." and replace with "study indicated that many primary care physicians miss..."

page 41, paragraph 2, line 7: do you want to add "businesses, churches, schools" etc. ?

page 42 → 44, paragraph 2, line 5: what type of "testing programs" ? Also the last sentence is problematic at the moment.

The following comments refer to the appendix:

In general, do you want to list the President's budget (in contrast to the Congressional approach)? Also, in listing constituency groups, it would read better to always list PLWAs first.

Page 3 (Care and Services): paragraph 9: The issue of formularies is tricky, a good idea, but one that is going to require some thought as to how we can do this without creating a system that subsidizes ~~Medicaid and private~~ managed care formularies. (?)

leads develop min. drug formulary for fed-assisted ADAP

paragraph 12: if this refers to the WIN projects, we now have 10 (3 funded with SPNS dollars.) (?)

paragraph 16: indicators not indicator

Page 4 Paragraph 3: In addition to these broad based efforts, HRSA also supports a variety of focused initiatives such as an adolescent research and clinical network and a cooperative.....

Page 4 Insert:

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

President's Budget

continue FY 96

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

paragraph 5: constituents are also represented on the HRSA AIDS Advisory Committee

paragraph 8: add, "working with NIMH, SAMSHA and other relevant agencies to insure access to mental health and substance abuse services" strike "to provide needed services."

Page 5

Add this paragraph:

From the point of view of the front line provider who may receive funding from several Federal agencies, a need for improved coordination within agencies and between agencies is often apparent. In addition, for example, to the lack of adequate resources for technical assistance and evaluation, there is also a need for improved planning and coordination of these activities between the various CARE activities and between Federal agencies.

Thanks again for the opportunity to review this document.

Sincerely,

Joseph F. O'Neill, M.D., M.P.H.
Associate Administrator for AIDS

TEXT

General Comments

- It would be helpful if an "introduction section" could be added to the National Strategy for HIV and AIDS (NSHA) that briefly explains what Federal Departments and independent agencies, and other groups outside the government were involved in the development of this strategy.

- There is a lack of consistency of terminology throughout the NSHA. This is the plan of the Executive Branch of the Federal Government, which includes a number of departments and agencies. The cover memorandum from the Director states that "I believe this document builds on this consensus and articulates the goals and objectives of the entire Federal Government." This may be stated as the "Executive Branch of the Federal Government" since it does not include any Congressional or legislative branch collaboration.

- Before the final NSHA is published, a version with all of the appendices should be circulated for review and final clearance.

Additional Comments

Page 2, paragraph 2, line 2 "This is the first time a government-wide national plan for the United States has been developed for fighting HIV." There have been plans developed earlier in the epidemic (see page 8, paragraph 3, line 1). It would be helpful, and more accurate, to explain as early in the document as possible why this "government-wide national plan" is different than previous plans developed at Coolfont, Charlottesville, and the PHS Strategic Plan.

Page 2, paragraph 5, line 1 "The purpose of this comprehensive national strategy is to set forth overarching national goals and priorities for 1996 in charting our course for combatting the epidemic of HIV and AIDS." It is not clear if the national strategy included collaboration with outside groups. Also, is it the calendar year 1996 or the fiscal year 1996?

Page 3, paragraph 2, line 13 "Medicare and Medicaid is being threatened by funding changes" could be edited to read "threatened by fundamental (or basic) programmatic changes and reductions in funding."

Page 3, paragraph 4, line 1 "The epidemic of HIV and AIDS threatens the economic progress of many countries around the world." What follows in the text is a short discussion of the United States only.

Page 6, paragraph 1, line 1 Footnote 1 (or 1a) - "It is anticipated that this trend could be reversed with the implementation of the PHS recommendations for the administration of AZT to women during pregnancy and to their infants after birth." Since taking AZT is an option, we may need to insert "potentially" before the word could. CDC's guidelines (July 1995) state "To reverse these trends (HIV infection increasing among women and thus becoming a leading cause of death among young children) HIV education and services for prevention and health care must be made available to all women."

* Could not find footnote *

Page 7, paragraph 2, line 6 "And unlike other persons with infectious diseases, many persons living with HIV to have been the target of violence, rejected by their families, and suffered discrimination based on their HIV status."
The discrimination is also based on sexual orientation. Also, strike the "to" after the word "HIV" in that sentence.

page 7, paragraph 3, line 1 In this context, "anytime" should be two words, "any time"

Page 8, paragraph 1, line 4 "To ensure efficient use of Federal, State, local, and private resources, it is imperative to plan and coordinate government-wide efforts." This statement is not clear - how does this strategy ensure efficient use of private and local resources?

Page 8, paragraph 2, line 1 "This is the first time a government-wide national strategy for HIV and AIDS for the United States has been developed." See earlier comments (above) about consistency in the name of the plan and which directly reflects whic Federal agencies or other organizations collaborated in its content. In addition, the text should include how State and local governments were involved in its formulation.

Page 8, paragraph 3, line 2 "To date, planning has been primarily focused in the Public Health Service as evidenced by a series of documents such as..." These previous efforts have been

very briefly mentioned in the document. It should be noted and included that the Department of Health and Human Services delegated the responsibility to the Public Health Service to lead the effort to halt the AIDS epidemic. For readers unfamiliar with the Public Health Service, it may be helpful to include a footnote that it includes eight agencies, with the following seven NIH, FDA, CDC, HRSA, SAMHSA, AHCPR, IHS working on various aspects of the HIV/AIDS epidemic. The PHS is the lead Federal agency for health related issues. Also, while the Surgeon General's report on AIDS was not "technically" a plan, it is a benchmark of previous efforts. The public or the Congress may inquire of the NSHA document "How will the "National Strategy" plan be different from or have better results than previous efforts?"

Page 8, paragraph 3, line 9 "Recommendations have also been issued from a number of groups, including the National Commission on AIDS in addition to significant planning efforts on the part of individual agencies." The text, or a footnote, could be included to explain there were Congressionally legislated Commissions with Cabinet officers of different Executive Departments serving on these Commissions, including the Secretary of HHS. The HHS received the recommendations of these Commissions because of its health care mission.

Page 9, paragraph 1, line 15 "The insights provided by a number of groups including the National Commission on AIDS, the Institute of Medicine and National Research Council, the General Accounting Office, and the Office of Technology Assessment have also been helpful." It is not clear what insights were received. Since the Office of Technology Assessment has been eliminated by the current Congress, it may be better to refer to either specific reports or formal/informal collaborations these various entities have produced on HIV/AIDS or expert advice that they have offered.

Page 9, paragraph 1, line 18 "Therefore, the expertise and experience of those who work closely with communities, clinicians, researchers, service and research organizations, and infected persons is reflected in these goals and opportunities for progress." It appears from this statement that the "input" was "indirect" from these groups. Since this is

a Federal government document, it is anticipated that questions on the exact nature of the collaboration with groups and State and local governments will arise.

Page 9, bullet 3 — "Ensure appropriate care for and ethical treatment of persons with AIDS." It is not clear what "ethical" treatment involves in this context. Also, it should read "persons living with HIV/AIDS."

Page 9, paragraph 3, line 6 — "There was also a common sense that these challenges also represented opportunities for progress --..." Should "common sense" instead read "common objective" or "common goal?"

Page 10, paragraph 3, line 16 — "As a result, people with AIDS now live twice as long as they did a decade ago." Survival time in patients with AIDS is believed to have increased considerably during the past few years. There needs to be some context given to this statement, since it is 15 years since the beginning of the epidemic. Treatment (depending on access to care and when in the course of the disease an individual presents for care) and the course of the disease still varies. "Long term AIDS survivor" is a cruelly relative term. Most people infected with HIV take about 7 years to develop symptoms and 8 or more years to fit a diagnosis of the disease. But even with the best available treatment for AIDS, half the patients die within 2 years of being diagnosed and few live beyond 3.

According to the research literature, women and minorities may have a greater risk of a relatively early death but suggest that important factors may involve poorer access to or use of health care resources. The latest survival information can be updated by NIH and CDC.

Page 12, paragraph 1, lines 1-6 — "The scope and nature of the HIV/AIDS epidemic has brought state, local, and Federal involvement into many AIDS-related activities. The Federal government, through its public health responsibilitities in such areas as research, prevention, health care and housing has seen a dramatic increase in Federal activities since the beginning of the epidemic." The meaning of these two sentences are not clear. In the context of the overall HIV/AIDS epidemic, the Federal government, through HHS, devoted increased resources to address HIV and

AIDS through prevention, research, and services. HUD funding for the Housing Opportunities for Persons with AIDS (HOPWA) was not provided until FY 1992. HHS and HUD have collaborated on housing. Also, the Congress legislated certain funding and programs throughout the epidemic, some with certain restrictions included (e.g., needle exchange, content of education material). The NHSA is based on the knowledge and experience gained in facing the challenges of the HIV epidemic during the 1980s. Clarification is needed.

Page 12, paragraph 2, line 13 "In this case, programs that are specifically targeted towards countries or regions, are included in the international section." Insert "geographic" in front of regions and insert "of the world" after "regions" if this is the intent.

Page 12, paragraph 3, line 5 "There are number of agencies for whom AIDS-specific activities are central to their mission (e.g., the National Institutes of Health (NIH), the Centers for Disease Control and Prevention (CDC), and the Health Resources and Services Administration (HRSA))..." The agencies mentioned are all Public Health Service agencies, that are part of the Department of Health and Human Services. Each of these agencies has health-related missions that encompasses its HIV-related missions.

Page 13, paragraph 1, line 2 ...while other agencies maintain programs and activities that support a broad range of activities, of which HIV-related activities are one among many (e.g., the U.S. Agency for International Development (USAID) and the Department of Justice (DOJ))." The agency and Department mentioned are outside the Department of Health and Human Services, Public Health Service, which was given the lead early on in the AIDS epidemic, because of its health-related mission. As noted in comments (above), the NSHA should clarify the extent of the role of HHS (especially the PHS agencies and HCFA) and then note the relative role of other Departments and independent agencies.

Page 13, paragraph 2 The description of how the report is organized may be confusing. Since HIV/AIDS is a cross-cutting issue across seven of the eight Public Health Service Agencies

that comprise the PHS and HCFA in the Department of Health and Human Services, and further involves a number of cabinet level Departments: Veterans Affairs, Defense, State, for example, and other independent, free-standing agencies, it is recommended that the Office of the National AIDS Policy Director ensures the entire report (including ALL appendices) are provided for comment and review before publication.

Page 14, paragraph 3, line 1 "Prevention activities are currently supported by several Federal agencies. Most Federal prevention efforts are funded by the Public Health Service, although other departments such as the Department of Defense (DoD), and the Department of Veterans Affairs (VA) also support prevention activities." Insert the "HHS" after Public Health Service and see earlier comments to clarify agencies within the same Department early on in the NSHA.

Page 15, paragraph 2, line 1 "The efforts of Federal agencies have been instrumental in expanding our knowledge base about HIV prevention. However, significant gaps remain." After the word "agencies" insert "and Federally funded research, as well as research conducted at universities and private organizations."

Page 16, paragraph 2, line 1 "A crucial part of effective prevention strategies includes supporting adequate surveillance of HIV infection and related diseases in order to estimate the burden of HIV illness, gauge future directions of the epidemic, and assess the effectiveness of prevention activities." Potentially, this sentence on surveillance could be interpreted as used to provide economic estimates of "the burden of HIV disease." In general, efforts have been made NOT to further stigmitize HIV and AIDS by emphasizing costs. We have recognized, given the wide variability in both the course of HIV and AIDS and the new treatments (including drugs), that often private third-party payors do not reimburse for the cost of care for patients with HIV/AIDS and instead shift costs to the public sector which includes Federal programs.

Page 20, paragraph 1, line 1 "As President Clinton has noted, the epidemics of substance abuse and HIV in this country are overlapping and highly interrelated so we must work to integrate HIV prevention into current substance abuse programs

and integrate substance abuse prevention into HIV prevention." It may be appropriate to insert the words "continue to" after "must" since, for example, the Association of State and Territorial Health Officials (ASTHO) and the National Association of State Alcohol and Drug Abuse Directors (NASADAD), along with SAMHSA, CDC, HRSA, and NAPO sponsored the "National Conference on HIV and Substance Abuse" in November 1990 and the National Commission on AIDS issued a report entitled "The Twin Epidemics of Substance Abuse and HIV" in July 1991.

Page 21, paragraph 1, line 1 "...reflects the importance of integrating these inter-dependent aspects of the epidemic and illustrates our determination to integrate and coordinate HIV, STD and TB programs." It is not clear how the reorganization reflects "our determination."

Page 22, paragraph 1 In the discussion of incorporation of sexual history and prevention counseling, mention should be made of the need for training to improve primary care providers' skill, comfort level and sensitivity in this area.

Page 23, section on Research The overall role of the Department of Defense in research needs to be expanded in the text, unless it is clear from the appendices.

Page 23, paragraph 2, line 11 "The Agency for Health Care Policy and Research (AHCPR) funds research to help determine which medical approaches are the most cost effective." After the word "funds" insert "health services."

Page 23, paragraph 3, line 1 "The Nation has already reaped the benefits of supporting research in general, and HIV-related research specifically." Insert the words "some of" before "the benefits". Also, this sentence could be edited to include not only the national impact, but the international impact.

Page 24, paragraph 3, line 1 "Due in great part to this Federally-sponsored research, persons with AIDS now live twice as long as they did a decade ago." Please see earlier note on survival.

Page 25, paragraph 2, line 5 "--mankind has never before encountered a virus such as this." According to NIH, changes in microbes and our environment will continue to present new health challenges worldwide. This sentence is not clear.

Page 26, paragraph 2, line 14 "...one of the areas identified by ADDTF and the Department of Health and Human Services members for further discussion was vaccine development." See previous comments regarding the consistency of the use of the Department of Health and Human Services. In this context, it is recommended that NIH and FDA, and other agencies that participated in the ADDTF be specifically cited.

Page 28, paragraph 2, line 3 "...numbers and at record speed,..." The term "record speed" could be better defined.

Page 28, paragraph 3, line 1 "With the advent of accelerated approval by the FDA it is incumbent on the government to ensure that the post-marketing efficacy studies, currently mandated through regulation are carried out." This needs to be rewritten to clarify that FDA/PHS/HHS is charged with this responsibility.

Page 28, paragraph 3, line 12 "As a result, patients may be receiving less effective treatment or combinations of treatments, and Federal programs such as Medicaid and Medicare and Private insurers may be paying for these less effective treatments. Americans are spending millions of dollars per year on such therapies about which little is known." These sentences are not clear and could potentially be interpreted as a reason to <u>not</u> pay for clinically indicated therapies, and involve several complex issues, including, allowing clinical trials to use surrogate markers of disease progression and of drug efficacy. Also, the Ryan White CARE Act reimburses for prescription drugs.

Page 33, paragraph 1, line 1 "...Treatment and primary care must come before ancillary services." The document may need to define "ancillary." This statement could have far reaching policy implications, especially for the AETC Program. The Senate Appropriations Committee language appears to indicate the Senate's desire to move the decision for

funding provider training to the local planning bodies. "Increasing access to, and support of, treatment and primary care...." would be a better choice of words.

Page 33, paragraph 4, line 11 "...schools, and professional organization in addition to local and Federal governments." Insert "State" after the word "local."

Page 35, paragraph 1 Four of the five agencies provided as examples in this paragraph reside in the Department of Health and Human Services, Public Health Service (SAMSHA, HRSA, CDC and NIH). While uniform applications are administratively possible, the statutes and regulations may have to be amended to accomplish this.

Page 38, paragraph 1, line 5 "Based on the Vice President's initiative to bring the lessons back home through the "Lesson without Borders Project" to inner city and rural areas with problems similar to those experienced overseas,..." A footnote to this project may be necessary to those who are not familiar with its content (source and date).

Page 40, paragraph 1, line 5 "NIH's state-of-the-art conferences have also contributed to improving the translation of research results into clinical practice." Examples of what these "state-of-the-art" conferences are and when they were held would be useful (it could be as a footnote).

Page 41, paragraph 3, line 16 "The Health Care Financing Administration (HCFA) also enforces regulations regarding the treatment of HIV-infected persons." This appears to be the first time this agency, an agency in the Department of Health and Human Services that adminsters the Medicare and Medicaid programs is specifically mentioned. Also, the NSHA needs to clarify how the HCFA regulates (perhaps an example could be included).

Page 42, paragraph 2, line 8 "The Administration will also continue to oppose Congressional attempts to force discharge of infected military personnel who are still able to serve their country." Since the Defense Department's bill has already been signed by the President, this sentence needs to be modified and include the Departments that will be taking the lead in this effort.

(Care and Services)

Page 4, paragraph 1, line 3	Add to "evaluate program effectiveness." "...Agree to common evaluation criteria of CARE Act grants that address program delivery and program outcomes. Also establish evaluation measures that are unique to each Title."
Page 4, paragraph 5	Add to "constituency involvement:" "Nationally, focus groups, workshops, and discussion groups of PWAs, providers of HIV care, State and local officials, and researchers review proposed policies, program directives, and planning and evaluation activities to ensure constituency input."
Page 4, paragraph 8	Unmet Need: Add "...There is need for increased access to 1% evaluation funds for service-related evaluations."
page 6	Regarding question: Are there separate funds for the SPNS evaluation? Answer: ~~No, all of the funds come from 10% tap from Title II.~~ Add: Objective: Ensure funding and dissemination of innovative models of care that evaluate all of the major care and service goals listed in this plan: effectively educated providers, increased access to and quality of care, reduction of perinatal transmission of HIV. Action Steps: Review currently funded SPNS projects to identify gaps in project coverage for future Requests for Applications (RFAs). Populations served: CARE Act grantees. Constituency Involvement: Health care providers, evaluation researchers, communication experts, and patient advocates.
page 9	I would suggest adding this to unmet need under the reduction of perinatal transmission: " In particular, it is

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

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

EXECUTIVE SECRETARIAT

FACSIMILE

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

NAME: Jane Harrelle

ADDRESS: _____

MESSAGE: _____

FAX NUMBER: _____

OFFICE NUMBER: _____

FROM: **GLEN HARELSON**
POLICY COORDINATOR

FAX NUMBER: **202 690-7203**

OFFICE NUMBER: **202 690-7699**

NUMBER OF PAGES (INCLUDING THIS ONE): 3

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
Rockville MD 20857

MEMORANDUM

Date: March 6, 1996

To: Patricia S. Fleming
Director, Office of National HIV/AIDS Policy

From: Theresa A. Toigo, RPh, MBA
Associate Commissioner for AIDS and Special Health Issues
Food and Drug Administration

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With respect to the unmet needs, the Prescription Drug Use Fee Act of 1992 authorized FDA to receive the additional resources needed to expeditiously review HIV/AIDS related therapeutic applications.

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

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

EXECUTIVE SECRETARIAT

FACSIMILE

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

NAME: Jane Horvath

ADDRESS: _____

MESSAGE: _____

FAX NUMBER: _____

OFFICE NUMBER: _____

FROM: **GLEN HARELSON**
POLICY COORDINATOR

FAX NUMBER: **202 690-7203**

OFFICE NUMBER: **202 690-7699**

NUMBER OF PAGES (INCLUDING THIS ONE): 3

PHOTOCOPY PRESERVATION

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
Rockville MD 20857

MEMORANDUM

Date: March 6, 1996

To: Patricia S. Fleming
Director, Office of National HIV/AIDS Policy

PHOTOCOPY PRESERVATION

From: Theresa A. Toigo, RPh, MBA
Associate Commissioner for AIDS and Special Health Issues
Food and Drug Administration

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

Thank you for the opportunity to comment on the draft National Strategy for HIV and AIDS document. We have suggested revised wording for sections of the document which specifically address FDA's activities. These suggested revisions are listed below. In addition, we do not think that this document reflects all of FDA's significant HIV/AIDS prevention and research related activities. Examples of additions to the document you may want to consider include a discussion of the development of new materials for barrier products, evaluation of new types of HIV test kits, expanded access programs for people who can not enroll in controlled clinical trials, and blood safety initiatives. Please let me know if you would like us to submit draft language for any of these subject areas.

FDA has not received final budget figures for FY 96. As of today, FDA is straight lining our AIDS budget figures from FY 95 budget figures. We expect to receive final FY 96 budget figures in the next couple of weeks.

Comments on the FDA references in the draft document:

Page 26, Vaccine Development - This section mentions the National AIDS Drug Development Task Force (ADDTF). The correct name of this task force is the National Task Force on AIDS Drug Development (NTFADD). Vaccine development was outside of the Task Force charter and the members did not make any formal recommendations regarding vaccine development. We do not think there should be any reference to the NTFADD in the vaccine development section.

Page 28, Footnote 4 - We suggest the following language be used for this footnote.

> The accelerated approval regulation permits companies to seek approval of new drugs for serious or life-threatening diseases when the drug provides meaningful therapeutic benefit over existing therapies. Under these procedures, FDA may approve drugs based on surrogate endpoints, such as CD4+ cell counts that reasonably predict that a drug provides clinical benefit. The company then is required to confirm this clinical benefit through additional human studies that will 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.

Page 39, Translation of Science into Practice: This section discusses NIH's support of the AIDS Clinical Trials Information Service (ACTIS), 1-800-TRIALS-A. FDA, along with other DHHS/PHS agencies, are cosponsors of this toll-free information service. We suggest making ACTIS a separate sentence mentioning each of the agencies involved, NIAID, FDA, CDC, and the NLM.

Comments on the FDA Appendices:

Each of our appendices should contain the same Constituency Involvement wording. We suggest the following paragraph:

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

With respect to the unmet needs, the Prescription Drug Use Fee Act of 1992 authorized FDA to receive the additional resources needed to expeditiously review HIV/AIDS related therapeutic applications.

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

PEACE CORPS
OF THE UNITED STATES

FACSIMILE TRANSMISSION COVER SHEET

DATE: April 8, 1996

TO: Jane Sandle
White House AIDS Policy Office

FROM: Shelley Smith
Peace Corps-

FAX#: 202/632 ~~1090~~ 1096

FAX #: (202) 606-3024

PHONE: _____

PHONE: (202) 606-~~3477~~ 3765

Number of pages in transmission (including cover sheet) 2

URGENT MESSAGE: YES _____ NO X

SUBJECT

REMARKS Jane -

A slight addition to the statement on PC's work. Let me know if you have questions.

Shelley

Peace Corps' Activities

Peace Corps trains a growing number of its Volunteers to directly address HIV related concerns, as well as, to integrate HIV/AIDS education into other services, such as the teaching of English, in their country of placement.

United States Information Agency

Washington, D.C. 20547

Office of the Director

USIA

March 29, 1996

Ms. Jane Sanville
Office of National AIDS Policy
750 17th Street, N.W.
Suite 600
Washington, D.C. 20503

Dear Jane:

As we discussed, USIA clears the February 6 draft of the National Strategy for HIV and AIDS. Thank you for accurately putting our submission into the required format.

If your office has any further questions on USIA programs dealing with HIV and AIDS, please do not hesitate to contact me.

Sincerely,

Jess L. Baily
Senior Advisor for Global Issues

UNITED STATES DEPARTMENT OF EDUCATION

OFFICE OF ELEMENTARY AND SECONDARY EDUCATION

March 6, 1996

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

From : William Modzeleski
Director, Safe and Drug Free Schools Program

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

As requested, we have reviewed the Draft National Strategy for HIV and AIDS and have the following comments:

- A final FY 1996 budget for the Department of Education has not yet been passed by Congress therefore no budget figures are available to include in the Plan. It should be further noted, that if ED receives significant reductions in those programs that deal with HIV/AIDs the Plan may need to be modified to reflect the decrease. For example, the current House and Senate proposals (not the CR), call for complete elimination of all discretionary grant funds for the Safe and Drug Free Schools Program. If this occurs, or if there are substantial decreases in funding, we will not be able to prepare a publication on the relationship between HIV/AIDS and drug use.

- The plan included in the appendix is considerably different than the one submitted last year, are we to assume that agencies are to concentrate their efforts on what is included in this draft?

Comments regarding the plan included in the Appendix follow.

- In the Department of Education appendix, Objective 1, Action Step #2, should read: Include information related to school-based comprehensive health programs (ED funded) in the Comprehensive Health Information Database (HHS).

  Names of programs that would be shared with HHS were included in Attachment A of our original submission.

  Constituency Involvement: Majority of ED programs are developed at local level and therefore there is little involvement of constituency groups at the Federal level.

- Objective #2, It is uncertain whether any publications will

be developed. Our original submission was developed prior to our current budget. It is unlikely that we will have discretionary funds to develop any new publications.

No budget figures are available for 1996.

Populations served: the write up is accurate.

If there are any questions regarding our comments please contact me. My direct line is 260-1856.

① The State dept. appendix is under N:\Lattoma\State.E96

② language for the N:\WP\OUTLINE20.TXT

Lattoma's comments

United States Department of State

Bureau of Oceans and International Environmental and Scientific Affairs

Washington, D.C. 20520

March 1, 1996

Ms. Patricia S. Fleming
Director, Office of National AIDS Policy
Executive Office of the President

Dear Patsy:

Thank you for the opportunity to comment on the draft National Strategy for HIV and AIDS. The document is comprehensive and includes an accurate description of the efforts underway by several agencies to ensure that the AIDS pandemic is addressed on a global scale. The document refers to the interagency effort that led to the development of an International Strategy on HIV and AIDS, and includes the actions that are most critical to move this strategy forward.

Under the resources section of the document, you seek clarification of several points. With regard to funding for the UNAIDS program, you should direct questions in this area to USAID. More generally, you ask about the capacity of the State Department to staff the international actions identified in the international strategy. While the OES Bureau continues to serve a coordinating role in implementing the strategy, practically speaking we lack the personnel necessary to move these actions forward in a timely fashion. Given the current budget and personnel constraints within our Department, I do not foresee a near-term change in this situation. I consider this to be a major obstacle to progress in working with our foreign counterparts to address the pandemic.

We will be seeking every possible means within our existing resources to fulfill the goals of the international strategy; however, your concerns about staffing as expressed in your draft document are indeed valid. I welcome your thoughts on ways to address this problem.

Sincerely yours,

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

INTERNATIONAL ACTIVITIES

Agency: U.S. Department of State

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

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

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

Description: Initiative to increase commitment of foreign leaders.

FY 95: NA
FY 96: NA

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

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

Unmet Needs: Staffing issues?

Budget and personnel constraints limit ability to coordinate actions identified in the international strategy document

Agency: U.S. Department of State

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

Does the State Department provide the U.S. contribution to UNAIDS? NO

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

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

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

FY 95: NA
FY 96: NA

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

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

Unmet Needs: Staffing issues?

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

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

Description: Improving U.S. responsiveness.

FY 95: NA
FY 96: NA

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

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

Unmet Needs: Staffing issues?

Agency: U.S. Department of State

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

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

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

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

FY 95: NA
FY 96: NA

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

Constituency Involved: U.S. State Department.

Unmet Needs: Staffing issues?

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

Action Steps: Distribute International Strategy on HIV/AIDS to embassy personnel; the Global Implications of HIV/AIDS
→ held a workshop. → HIV/AIDS
Use training sessions and individual briefings of foreign service personnel to discuss HIV/AIDS as a foreign policy concern;

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

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

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

FY 95: NA
FY 96: NA

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

Constituency Involved: U.S. State Department.

Unmet Needs: Staffing issues?

Agency: U.S. Department of State

Goal: Support U.S. technical agencies.

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

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

Description: Support for international research.

FY 95: NA
FY 96: NA

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

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

Unmet Needs: Staffing issues?

Cattanach Comments

INTERNATIONAL ACTIVITIES

AIDS is a global pandemic. In the United States it is estimated that between 800,000 and 1 million people are currently infected with HIV. The World Health Organization (WHO) estimates that 18.5 million adults and over 1.5 million children are currently infected worldwide. WHO also estimates that two to three million new HIV infections can be expected annually, and by the year 2000, thirty to forty million people will have been infected around the globe.

This pandemic presents a unique set of health, social, economic, and political challenges. It most often affects people aged 25 to 44 -- those who are in the most productive years of life. The period from initial infection to disease onset can be many years, during which time persons many unknowingly spread the infection. The WHO estimates that there will be 10 to 15 million orphans worldwide attributable to HIV/AIDS by the year 2000. In Africa and Asia, economic advances are threatened, and in some cases, may be reversed due to the pandemic of HIV and AIDS. Socio-economic studies have shown a decrease in overall domestic savings and investment levels, negative effects on foreign investments, reductions in the volumes of imports and exports, and a reduction in receipts from tourism.[21] 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.

Due to the global nature of the pandemic, its negative impact on both developed and developing countries cannot be overstated. It is clear that if we do not stop the pandemic globally, we will not be able to halt its spread in the United States.

At present several Federal agencies are working on slowing the AIDS epidemic worldwide. (See Appendix D.) The Department of State has worked with other departments, agencies, and non-governmental organizations to develop a framework to guide U.S. foreign policy in the global efforts against HIV and AIDS. The major areas identified for U.S. leadership are: preventing new infections; reducing the personal and social impact of the pandemic; and mobilizing and unify national and international efforts. The U.S. Agency for International Development (USAID) also has a leadership role in the global HIV effort through development assistance, research and policy formation. USAID focuses its strategy on developing prevention programs based on proven interventions, addressing social, cultural, regulatory and

economic issues related to HIV/AIDS and other sexually transmitted infections, and developing and testing new interventions and methods to prevent transmission and mitigate the impact of the epidemic. The U.S. Information Agency (USIA) supports programs that promote dissemination of U.S. policies and information related to HIV and AIDS; and the Peace Corps trains a portion of its volunteers to directly address HIV-related concerns in their countries of placement. In addition, several agencies support research overseas, including the National Institutes of Health, the Centers for Disease Control and Prevention, and the Department of Defense (DOD). For example, DOD is conducting clinical trials of candidate HIV vaccines in Thailand. NIH (working in collaboration with USAID), supports basic scientific studies on social and behavioral aspects of AIDS 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.

HHS/PHS

leave out

Opportunities for Progress

International Leadership. The United States has established a global leadership role in combatting the epidemic. This leadership must continue. The U.S. strongly supports the newly established Joint and Co-sponsored United Nations Programme on AIDS (UNAIDS)[5] . Moreover, the U.S. is a member of the governing body of UNAIDS. Supporting UNAIDS demonstrates the continuing commitment of the U.S. to collaborate with other countries in lessening the impact of the epidemic. The U.S. also supports efforts to more effectively make use of available resources as well as to encourage non-traditional donor countries to provide much needed contributions. Supporting UNAIDS and its innovative programmatic efforts, and its goal of working to assure that therapeutics (and vaccines when developed) are made available to the residents of developing countries is not only morally correct, but also furthers U.S. interests by promoting economic and social stability worldwide.

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[5] Until recently, the United Nation's response to HIV/AIDS was focused primarily in WHO's Global Programme on AIDS. On January 1, 1996 the U.N. launched UNAIDS, combining the efforts of six U.N. agencies to stregthen coordination and focus support for HIV/AIDS activities at the country and global levels. UNAIDS has established three mutually reinforcing roles: to be a major source of policy development and research; provide technical support; and be an advocate for comprehensive, multisectoral responses to the pandemic.

Sharing Technology and Bringing Lessons Home. In addition to financing the development of large scale, comprehensive AIDS prevention programs in many countries, USAID has gained valuable insights and lessons from experiences from these countries and is applying them to U.S. populations. Based on the Vice President's initiative to bring the lessons back home through the "Lesson without Borders Project" to inner city and rural areas with problems similar to those experienced overseas, the goal is to create linkages between U.S. community organizations and international projects in order to share solutions to problems that know no borders. The U.S., through its various agencies will continue to build and strengthen networks that will facilitate leadership, coordination and transnational approaches to AIDS prevention and control programs and AIDS related research; exchange culturally and linguistically appropriate educational and training materials; and demonstrate the bidirectionality of USAID international programs and its potential impact on US based programs, U.S. based non-governmental organizations and indigenous groups.

Program Coordination. One of the most challenging aspects of the U.S. effort is effective coordination among a host of agencies with varied missions and activities. The State Department, ~~and~~ HHS and agencies such as USAID and USIA are primarily focused on country-specific activities that include many HIV-related objectives. Agencies which conduct research, such as NIH and CDC, plan their activities not around where they take place, but around scientific gaps and interests. These differences in focus present challenges in effectively planning, coordinating, and evaluating the overall U.S. international effort. Therefore, in order to improve this endeavor, the agencies supporting international activities on the Interdepartmental Task Force for HIV and AIDS must develop a mechanism for identifying and coordinating this effort.

Revised USAID, based on their fax, attached,

INTERNATIONAL ACTIVITIES

Agency: U.S. Agency for International Development

Goal: Sustainable reduction in sexually transmitted infections (STIs)/HIV transmission among key populations.

Objective: Develop and test new interventions and methods to prevent transmission and mitigate the impact of the epidemic.

Action Steps: Support research to identify activities that immediately and directly influence the effectiveness of existing programs.

Undertake activities that enable women to reduce the risk of HIV infection.

Undertake pilot projects and research to mitigate the impact of HIV in severly affected areas.

Undertake activities that support the public health infrastructure and utilization of HIV vaccines.

Description: * Development and ~~improvement~~ enhancing women's access to female controlled barrier methods of ~~woman controlled technologies~~. Improvement of STD/HIV prevention interventions and of technologies for STD management. **Does this section correspond with USAID's present goals???**

FY 95: Not available
FY 96: Not available

Population Served: Persons living in USAID's HIV/AIDS emphasis countries.

Constituency Involvement: USAID agency employees, developing country representatives, community representatives, PVO/NGO donors, multilateral donors and other bilateral donors.

Unmet Needs: Given the limited resources available for international development assistance, it is not possible for USAID to meet all the needs in this area.

* Priority given to studies that improve understanding of behaviors and epidemiology; operations research to test interventions to mitigate the impact of HIV/AIDS on communities; and facilitating opportunities for international field trials of promising vaccines

INTERNATIONAL ACTIVITIES

Agency: U.S. Agency for International Development

Goal: Sustainable reduction in sexually transmitted infections (STIs)/HIV transmission among key populations.

Objective: Develop and implement HIV/AIDS prevention programs that utilize proven interventions to prevent transmission.

Action Steps: Promote safer sexual behavior through information, education, and communication.

Increase the demand for, access to and use of condoms.

Control STIs by improving STI with diagnosis and treatment services and by education of persons with STIs.

Description: ~~Improvement of social and cultural commitment to HIV/AIDS prevention.~~

FY 95: Not available
FY 96: Not available

Population Served: Persons living with AIDS in USAID HIV/AIDS emphasis countries.

Constituency Involved: USAID agency employees, developing country representatives, community representatives, PVO/NGO partners, multilateral donors and other bilateral donors.

Unmet Needs: Given the limited resources available for international development assistance, it is not possible for USAID to meet all the needs in this area.

* Strengthening and expanding communication programs to influence social norms and create a more supportive environment for behavior change; Expanding condom demand and use; Improving the quality of diagnosis + treatment, increasing access to services including counseling, training for care providers and facilitating the procurement of drugs.

INTERNATIONAL ACTIVITIES

Agency: U.S. Agency for International Development

Goal: Sustainable reduction in sexually transmitted infectious (STIs)/HIV transmission among key populations.

Objective: Enhance capacity of public, private NGO and community based organizations to design, implement and evaluate effective HIV/STI prevention and care programs.

Action Steps: Improve policy reform, research capability, logistics systems, and use of local and regional NGO networks.

Enhance the technical and managerial capability of indigenous NGOs and PVOs to design, implement and evaluate HIV/STI projects in all HIVAIDS emphasis countries.

Strengthen local and regional networks of NGOs involved in HIV prevention, care and advocacy in at least six countries.

Assess and strengthen host country capacity for HIV/STI prevention research.

Disseminate models of home and community based delivery of HIV/STI care.

Description: * ~~Increased support for UNAIDS' expanded response to HIV/AIDS in developing~~ countries.

FY 95: Not available
FY 96: Not available

Population Served: Persons living in USAID's HIV/AIDS emphasis countries.

Constituency Involved: USAID agency employees, developing country representatives, community representatives, PVO/NGO partners, multilateral donors and other bilateral donors.

Unmet Needs: Given the limited resources available for international development assistance, it is not possible for USAID to meet all the needs in this area.

* ~~Continue to collaborate with and direct the support of the efforts of multilateral orgs such as UNAIDS, WHO, UNDP, UNICEF, UNFPA, for HIV/AIDS prevention~~ VS-Japan Common Agenda

* Continue to support the Paris Summit Initiative; the Greater Involvement of Persons Infected and Affected by HIV/AIDS (GIPA); Prioritize funding to indigenous NGOs and strengthen linkages between indigenous

NGOs and US domestic PVOs, NGOs and ASOs; Concentrating bilateral and core resources to assure comprehensive programs; on a limited number of emphasis countries and strengthening trans-national and regional activities in prevention and research through the "areas of affinity" concept; Continue to collaborate with and directly support the efforts of multi-lateral organizations such as UNAIDS, WHO, UNDP, UNFPA and UNICEF; US-Japan Common Agenda for HIV/AIDS prevention.

INTERNATIONAL ACTIVITIES

Agency: U.S. Agency for International Development

Goal: Sustainable reduction in sexually transmitted infectious (STIs)/HIV transmission among key populations.

Objective: Policy reform addressing social, cultural, regulatory and economic issues related to HIV/AIDS and other STIs.

Action Steps: Conduct policy dialogue with decision makers to encourage a high-level multi-sectoral coordinated response to HIV/AIDS.

Address resource issues and long-term sustainability at all levels.

Address the social and cultural impediments to the successful implementation of HIV/AIDS programs.

Develop tools and complete research to serve policy dialogue and reform.

~~**Program** **Description:**~~ * ~~Increasing the use of~~ methods aimed at ~~reducing perinatal and parenteral~~ HIV transmission.
~~**There was not a revised Program Description section-should this be taken out, and if so what should replace it?**~~

FY 95: Not available
FY 96: Not available

Population Served: Persons living in USAID's HIV/AIDS emphasis countries.

Constituency Involved: USAID agency employees, developing country representatives, community representatives, PVO/NGO partners, multilateral donors and other bilateral donors.

Unmet Needs: Given the limited resources available for international development assistance, it is not possible for USAID to meet all the needs in this area.

* Coordinating effective donor response and leveraging funding; Supporting international and regional, multi-sectoral approaches; mobilizing the private sector; Supporting decision-makers to address different social, cultural and religious issues; Continuing to develop and use tools such as simulation modelling to demonstrate potential socio-economic impact of the epidemic.

JANE--THERE IS STILL NO REVISED SECTION HERE

Agency: U.S. Agency for International Development

Goal: Improve services for HIV/STD prevention and care in emphasis countries.

Objective: To increase knowledge, availability and quality of HIV/STD services in emphasis countries.

Action Steps: Increase knowledge to over 90 percent and 60 percent respectively in rural and urban general population adults.

Implement BCC programs and services to reach general population women in urban settings;

Use training protocols for promoting gender-, culture- and class-sensitive HIV/STD program design and implementation; and

Implement participatory community-based risk analysis and normative change interventions.

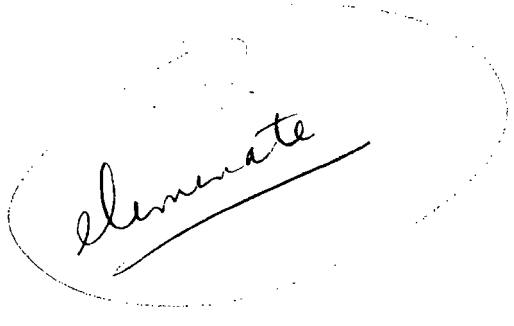
Description: Increased and improved implementation of behavior change communication interventions.

FY 95: Not available
FY 96: Not available

Population Served: USAID's HIV/AIDS emphasis countries.

Constituency Involved: USAID agency employees, developing country representatives, community representatives, multilateral donors and other bilateral donors.

Unmet Needs: Given the limited resources available for international development assistance, it is not possible for USAID to meet all the needs in this area.



Agency: U.S. Agency for International Development

Goal: Increase availability of HIV/STD services in emphasis countries.

Objective: To increase knowledge, availability and quality of HIV/STD services in emphasis countries.

Action Steps: Provide 25 percent more technically-sound condom marketing and logistics management programs;

Implement improved national-level strategies to provide STD services;

Perform global and regional analyses of STD data to assess trends and efficacy of interventions;

Increase demand for technically-sound STD services among urban adults in all USAID project areas;

Use approaches for the integrated and coordinated delivery of HIV/STD, FP and other RH services.

Description: Increased and improved services for HIV/STD prevention and care.

FY 95: Not available
FY 96: Not available

Population Served: USAID's HIV/AIDS emphasis countries.

Constituency Involved: USAID agency employees, developing country representatives, community representatives, multilateral donors and other bilateral donors.

Unmet Needs: Given the limited resources available for international development assistance, it is not possible for USAID to meet all the needs in this area.

INTERNATIONAL ACTIVITIES

Agency: U.S. Agency for International Development

Goal: Sustainable reduction in sexually transmitted infections (STIs)/HIV transmission among key populations.

Objective: Develop and implement HIV/AIDS prevention programs that utilize proven interventions to prevent transmission.

Action Steps: Promote safer sexual behavior through information, education, and communication.

Increase the demand for, access to and use of condoms.

Control STIs by improving STI with diagnosis and treatment services and by education of persons with STIs.

Description: ~~Improvement of social and cultural commitment to HIV/AIDS prevention.~~

FY 95: Not available
FY 96: Not available

Population Served: Persons living with AIDS in USAID HIV/AIDS emphasis countries.

Constituency Involved: USAID agency employees, developing country representatives, community representatives, PVO/NGO partners, multilateral donors and other bilateral donors.

Unmet Needs: Given the limited resources available for international development assistance, it is not possible for USAID to meet all the needs in this area.

* Strengthening and expanding communication programs to influence social norms and create a more supportive environment for behavior change; Expanding condom demand and use; Improving the quality of diagnosis + treatment, increasing access to services including counseling, training for care providers and facilitating the procurement of drugs.

INTERNATIONAL ACTIVITIES

Agency: U.S. Agency for International Development

Goal: Sustainable reduction in sexually transmitted infectious (STIs)/HIV transmission among key populations.

Objective: Policy reform addressing social, cultural, regulatory and economic issues related to HIV/AIDS and other STIs.

Action Steps: Conduct policy dialogue with decision makers to encourage a high-level multi-sectoral coordinated response to HIV/AIDS.

Address resource issues and long-term sustainability at all levels.

Address the social and cultural impediments to the successful implementation of HIV/AIDS programs.

Develop tools and complete research to serve policy dialogue and reform.

~~**Program** **Description:**~~ * ~~Increasing the use of~~ methods aimed at ~~reducing perinatal and parenteral~~ HIV transmission.
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Unmet Needs: Given the limited resources available for international development assistance, it is not possible for USAID to meet all the needs in this area.

* Coordinating effective donor response and leveraging funding; Supporting international and regional, multi-sectoral approaches; mobilizing the private sector; Supporting decision-makers to address difficult social, cultural and religious issues; Continuing to develop and use tools such as simulation modelling to demonstrate potential socio-economic impact of the epidemic.

Revised USAID, based on their fax, attached.

INTERNATIONAL ACTIVITIES

Agency: U.S. Agency for International Development

Goal: Sustainable reduction in sexually transmitted infections (STIs)/HIV transmission among key populations.

Objective: Develop and test new interventions and methods to prevent transmission and mitigate the impact of the epidemic.

Action Steps: Support research to identify activities that immediately and directly influence the effectiveness of existing programs.

Undertake activities that enable women to reduce the risk of HIV infection.

Undertake pilot projects and research to mitigate the impact of HIV in severly affected areas.

Undertake activities that support the public health infrastructure and utilization of HIV vaccines.

Description: * Development and ~~improvement~~ enhancing women's access to female controlled barrier methods of ~~woman controlled technologies~~. Improvement of STD/HIV prevention interventions and of technologies for STD management. **Does this section correspond with USAID's present goals???**

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Population Served: Persons living in USAID's HIV/AIDS emphasis countries.

Constituency Involvement: USAID agency employees, developing country representatives, community representatives, PVO/NGO donors, multilateral donors and other bilateral donors.

Unmet Needs: Given the limited resources available for international development assistance, it is not possible for USAID to meet all the needs in this area.

* Priority given to studies that improve understanding of behaviors and epidemiology; operations research to test interventions to mitigate the impact of HIV/AIDS on communities; and facilitating opportunities for international field trials of promising vaccines

INTERNATIONAL ACTIVITIES

Agency: U.S. Agency for International Development

Goal: Sustainable reduction in sexually transmitted infectious (STIs)/HIV transmission among key populations.

Objective: Enhance capacity of public, private NGO and community based organizations to design, implement and evaluate effective HIV/STI prevention and care programs.

Action Steps: Improve policy reform, research capability, logistics systems, and use of local and regional NGO networks.

Enhance the technical and managerial capability of indigenous NGOs and PVOs to design, implement and evaluate HIV/STI projects in all HIVAIDS emphasis countries.

Strengthen local and regional networks of NGOs involved in HIV prevention, care and advocacy in at least six countries.

Assess and strengthen host country capacity for HIV/STI prevention research.

Disseminate models of home and community based delivery of HIV/STI care.

Description: * ~~Increased support for UNAIDS' expanded response~~ to HIV/AIDS ~~in developing~~ countries.

FY 95: Not available
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Population Served: Persons living in USAID's HIV/AIDS emphasis countries.

Constituency Involved: USAID agency employees, developing country representatives, community representatives, PVO/NGO partners, multilateral donors and other bilateral donors.

Unmet Needs: Given the limited resources available for international development assistance, it is not possible for USAID to meet all the needs in this area.

~~* Continue to collaborate with [illegible] of multilateral orgs such as UNAIDS, WHO, World Bank, UNICEF, UNFPA;~~ The efforts ~~US-Japan Common Agenda for HIV/AIDS prevention~~

* Continue to support the Paris Summit Initiative; the Greater Involvement of Persons Infected and Affected by HIV/AIDS (GIPA); Prioritize funding to indigenous NGOs and strengthen linkages between indigenous

U.S. Agency for International Development

Bureau for Policy and Program Coordination

FAX

TO: Jane Sanville
Phone: 632-1090
FAX: 632-1096
No. of pages (inc. this coversheet): 6

FROM: Beverly Nelson
Phone: 647-8383
FAX: (202) 647-8595

Message:

The missing page is the next to last page.

Attached: memo to Patsy Fleming
and four pages of appendix

...Please deliver upon receipt.

U.S. AGENCY FOR
INTERNATIONAL
DEVELOPMENT

February 16, 1996

MEMORANDUM

TO: Patsy Fleming, Director, Office of National AIDS Policy

FROM: Nils Daulaire, Deputy Assistant Administrator, PPC/PHD

SUBJECT: USAID comments on draft National Strategy for HIV and AIDS

Thank you for sharing the draft National Strategy for HIV and AIDS. This has been a considerable effort, and you and your staff should be commended.

Attached is a revision of the appendix concerning USAID's plans and objectives in HIV/AIDS. The version sent out for comment included an old list of USAID's goals and objectives for HIV/AIDS. The attached list is our current plan.

Please let me know if you have any questions.

VIA FAX
202 632-1096

5 pages

Agency: U.S. Agency for International Development

Goal: Sustainable reduction in sexually transmitted infections (STIs)/HIV transmission among key populations.

Objective: Develop and test new interventions and methods to prevent transmission and mitigate the impact of the epidemic

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undertake activities that enable women to reduce the risk of HIV infection

undertake pilot projects and research to mitigate the impact of HIV in severely affected areas

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Action steps: conduct policy dialogue with decision makers to encourage a high-level multi-sectoral coordinated response to HIV/AIDS

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OFFICE OF NATIONAL AIDS POLICY
EXECUTIVE OFFICE OF THE PRESIDENT

750 17th Street, NW
Washington, DC 20503

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

FACSIMILE COVER SHEET

PAGES INCLUDING COVER SHEET: 5

TO:	Beverly Nelson
FAX #:	647-8595
DATE:	3.18.96
FROM:	Jane Sanville

COMMENTS:

Attached is the fax we received from Mr. Daulaire -- one page is missing. I appreciate your assistance in tracking this down.

phone: 647 8383
Beverly Nelson
@ 647-8595

U.S. AGENCY FOR INTERNATIONAL DEVELOPMENT

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SDF P&O 7.

U.S. AGENCY FOR
INTERNATIONAL
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ENERGY

Dr. John Wooley - 202-586-0095

Ass. Director Energy Research

Asked him to call.

- Strategies →
  - Contributing research - supported by NIH
    to don't count that

I will send comments

Dr. Worley 2/26

RESEARCH

Agency: Department of Energy

Goal: Provide support for molecularly and mathematically oriented research, including HIV-related research.

Objective: In collaboration with other Federal agencies, provide access to sophisticated equipment and specially trained personnel.

Dr. Worley has not reviewed

Action Steps: In partnership with National Institutes of Health, support the HIV Sequence and Analysis Project at the Los Alamos National Laboratory (LANL); - Funding of database is NIH

Through the LANL, serve as the secondary laboratory for the World Health Organization's AIDS efforts;

Very well used

At Brookhaven National Laboratory, support synchrotron light sources and neutron beam facilities to assist researchers to characterize the structural configuration of HIV in order to aid in the development of novel therapies; and

Using mathematical biology, model how HIV spreads within an individual (in contrast to spread through populations) in order to provide fast, safe avenues for pursuing new theories about HIV and developing clinical and other experimental studies.

Descriptions: The HIV Sequence and Analysis Project, WHO secondary laboratory, Brookhaven National Laboratory resources.

FY 95: Part of DOE's general operating budget
FY 96: Part of DOE's general operating budget

Can't separate out.

Populations Served: Scientific community.

Constituency Involvement: ??? teams of HIV researchers prioritize →

Unmet Need: ???

→ Stable access to .... → Drug Cos. use beam line

Department of Energy
Washington, DC 20585

FACSIMILE TRANSMISSION COVER SHEET

DATE: 2/26/96

(202) 632-1096(F) 6--

TO: JANE SANVILLE, Don Donaldson
Paul Gilna (~~505~~)

FROM: DR. JOHN C. WOOLEY
ASSOCIATE DIRECTOR
OFFICE OF ENERGY RESEARCH
1000 INDEPENDENCE AVE S.W., RM 7B-084
WASHINGTON, DC 20585

VOICE: (202)586-0095
FAX: (202)586-1009

THIS TRANSMISSION CONSISTS OF 2 PAGE(S) INCLUDING THIS COVER SHEET. PLEASE CALL PATRICE PINKETT AT THE ABOVE NUMBER IF ALL PAGES ARE NOT RECEIVED.

REMARKS:

Research

Agency: Department of Energy ~~(DOE)~~

Goal: Provide infrastructure support for physical chemical research, termed structural biology, including indirect support for HIV-related research.

Objective: In collaboration with other Federal agencies, provide access to sophisticated equipment and specially trained scientific personnel.

Descriptions: The National Synchrotron Light Source at Brookhaven National Laboratory includes a Department of Energy supported x-ray beam line extensively used by structural biologists studying virus structure, including the structure of HIV. In addition~~al~~, through its National Laboratory system, DOE provides user facilities at other synchrotron light sources and at neutron beam facilities, which can be used by researches to characterize the structural configuration of intact HIV, and HIV's biochemical components, often in complexes with inhibitors. These studies ~~should aid~~ assist in the development of novel therapies, as well as advance our understanding of the pathogenesis and fundamental biology of HIV growth.

Action Steps: In collaboration with all relevant ~~All cognizant~~ agencies (NIH, NSF, DOE) and the scientists they support ~~have identified DOE as the prime source for~~ provide essential continued support ~~of these~~ for structural chemistry and biology facilities. ~~DOE should continue to~~ provide both the academic and the industrial community access to the facilities for further studies on the structural biology of HIV.

FY 95: Part of DOE's general operating budget.
FY 96: Part of DOE's general operating budget.
FY 97: "
Populations Served: Scientific community.

Constituency Involvement: Access to resources through peer review.

Unmet Need: Stable funding, guaranteed access for scientists to the facilities for the foreseeable future.

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U.S. DEPARTMENT OF LABOR
OASAM/ SAFETY AND HEALTH CENTER

IDTF / HIV-AIDS

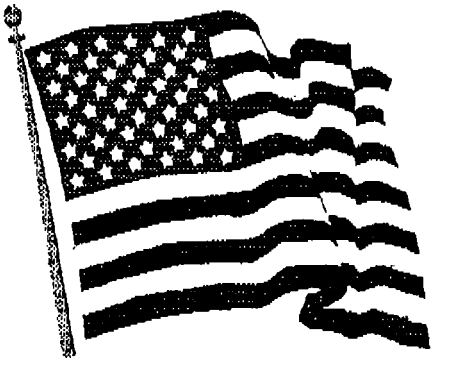
- TO: Jane Sanville DATE: FEB. 14 1996
- PHONE: 632-1090 FAX: 632-1096
- FROM: Henry Dorton

SUBJECT: Comments on "Redlined" Information (Nat'l Strategy for HIV and AIDS
TRANSMITTED ARE 3 PAGES (incl. cover)

REMARKS:

Page #2 is a copy of your questions pertaining to ESA/OFCCP
Page #3 is the response from ESA/OFCCP.

FAX: 202 219-4379
COMMERCIAL: (202) 219-6687



CIVIL RIGHTS

Agency: Department of Labor

Goal: To provide protection for people living with HIV and AIDS from discrimination.

Objective: To provide protection for persons living with HIV and AIDS from discrimination in the workplace.

Action Steps: Establish policies under Section 503 of the Rehabilitation Act of 1973 providing for processing and investigating complaints filed by persons living with HIV and AIDS.

Descriptions: Protection from discrimination in workplace.

FY 95: [redacted]
FY 96: [redacted]

Populations Served: Persons living with HIV and AIDS.

Constituency Involvement: Persons living with HIV and AIDS and Department of Labor staff.

Unmet Need: None.

Dorton Henry

From: Williamette Whiting
To: hdorton
Cc: wsw
Subject: National AIDS Policy
Date: Wednesday, February 14, 1996 12:40PM

Ref. the questions on the above subject:

1. There is no separate line item in the OFCCP budget for enforcement of Section 503. Specific costs cannot be distinguished or broken out for 95 or 96.

2. Unmet Need - OFCCP cannot provide any additional info. other than to say that there are no cases that OFCCP has not been able to process.

U.S. DEPARTMENT OF HOUSING AND URBAN DEVELOPMENT
WASHINGTON, D.C. 20410-7000

OFFICE OF THE ASSISTANT SECRETARY FOR
COMMUNITY PLANNING AND DEVELOPMENT

To: **Jane Sanville, Office of National AIDS Policy**

From: **David Vos, Office of HIV/AIDS Housing**

Date: **April 9, 1996**

Re: **Revisions to the Draft National Strategy for HIV and AIDS**

The Office of HIV/AIDS Housing offers the following comments and suggestions on the HUD-related sections of the draft national plan (February 6, 1996). These comments are also provided in a wordperfect 5.1 file, attached.

This office recommends more attention to housing issues in the draft report. It appears that the discussion of AIDS housing efforts of this Administration are limited to one paragraph on page 33. Additional information would more accurately reflect the accomplishments of the Clinton Administration in helping communities address the housing needs of PWAs as well as the significance that housing has in relation to the care and well being of persons living with HIV/AIDS. Additionally the format describes federal program efforts but does not seem to allow for a discussion of the community collaboration and leadership and individual private sector and volunteer efforts that created much of the AIDS housing efforts to date in this nation.

This office suggests that "Housing" be treated as a distinct section of the report, similar to international activities, or more visibly under the Care and Services section. This office is willing to assist in drafting this on an accelerated timetable.

The Department's previously submitted discussion on the HUD reinvention and its benefits to communities as well as residents who are living with HIV, was not included in the NAPO draft. I have attached that information in the attached wordperfect 5.1 file, if you would like to add additional information on these reinvention efforts. The following sections create a more general overview of the Federal Housing response. A clear statement on HUD's consolidated planning efforts, availability of mainstream programs as well as efforts targeted to persons with AIDS and other disabilities, and HUD's support for helping communities build comprehensive systems of homeless assistance, called continuum of care, would improve this draft, along the lines of the following overview:

Federal Housing Response.

Over the past three years, HUD Secretary Henry Cisneros and HUD senior staff have met regularly with AIDS housing providers and residents, as well advocates

for homeless people, persons with disabilities, service providers, and community leaders concerned about homelessness. In these early discussions, it became clear that efforts to address the needs of persons living with HIV/AIDS and to address and help prevent homelessness were not always reaching those persons in need and that additional actions were needed. Efforts were made to improve how all of HUD's programs can be made to be responsive in supporting communities in addressing the needs of their residents. HUD created an Office of HIV/AIDS Housing to administer a housing program for persons living with HIV/AIDS and their families and to improve the accessibility of other HUD programs.

In partnership with local initiatives, significant contributions have been made by programs that are targeted to the needs of persons with HIV/AIDS, such as the Housing Opportunities for Persons with AIDS (HOPWA) program. Since its inception in 1992, the HOPWA formula and competitive programs have distributed about one half billion dollars to communities for housing and services for persons living with HIV/AIDS. HOPWA funds have helped communities establish strategic plans, better coordinate local and private efforts, fill gaps in local systems of care, and created model programs. HOPWA funds may be used for a wide-array of housing, social services and program planning and development costs, including, but not limited to, the acquisition, rehabilitation or new construction of housing units, costs for facility operations, rental assistance and short-term payments to prevent homelessness. HOPWA may also support services, such as health care and mental health services, chemical dependency treatment, nutritional services, case management, assistance with daily living and other services. In a number of communities, HOPWA-funded programs were among the first efforts to provide housing assistance to persons living with HIV/AIDS.

In addition, the Clinton administration has made addressing homelessness a high priority. Persons living with AIDS are often at risk of homelessness and many who are homeless may be unaware of their HIV status. To better address these needs, funds for HUD homeless programs have tripled over the past three years. Additionally, HUD initiated a "Continuum of Care" approach to building local systems to address homelessness. The effort has resulted in significant leveraging of additional dollars to address this critical problem.

Additionally, many communities are part of new efforts to comprehensively plan for the housing needs of their residents, including assessing and addressing the needs of residents living with HIV/AIDS. The Consolidated Planning process for communities that receive funds under the Department's economic and community development programs, including recipients of HOPWA formula allocations. Consolidated planning involves citizen participation in assessing needs and creating a strategic plan. All communities are asked to identify needs of persons with HIV/AIDS and resources that may address those needs. The Community Development Block Grant (CDBG) and the HOME affordable housing program as

well as Public Housing programs are key resources that are available for this population, contingent on eligibility, space availability and local priorities. Additional efforts are underway to improve inter-departmental coordination as another important step in assisting communities to build seamless systems of support for our most vulnerable citizens.

As a further general comment on the draft report, no estimate is made on the proportion of any HUD program that is used to benefit persons living with HIV/AIDS. Eligibility for HUD programs is not based on the client's HIV status, except for the HOPWA program. Additionally, unmet needs are discussed under a general section and there is no explicit discussion of unmet needs under each of HUD's programs. Estimates of program funds which may become available in FY 1996 are provided, as the Department is not yet in receipt of its 1996 appropriations.

The following section would provide a general statement on unmet needs.

Unmet Housing Need: [add]

Housing is a daily need of every human. For persons living with the complications and challenges of HIV infection, the connection between housing and the well being of the person is profound and direct. As stated by the National Commission on AIDS in Housing and the HIV/AIDS Epidemic (issued in June 1992) there is "frequently desperate need for safe shelter that provides not only protection and comfort, but also a base in which and from which to receive services, care and support."

A number of AIDS housing developers and clients have recently provided additional information on the increasing gap between existing housing resources and the needs of potential clients living with HIV/AIDS. A survey conducted by AIDS Housing of Washington, Looking for a Place to Be: a report on AIDS housing in America (AHW, March 21, 1996) provides recent data based on a survey of 1,111 known providers and developers of housing assistance for persons with HIV/AIDS as well as over 2,500 persons with HIV/AIDS who are recipients of this assistance in six communities. The report found five common trends: (1) chemical dependency; (2) homelessness and risk for homelessness; (3) poverty and little affordable housing; (4) strong preference for independent living; and (5) small communities and rural areas increasingly affected. The survey data illustrated these trends:

> Over a third (36%) of people with AIDS have been homeless since learning of their HIV infection or AIDS; from 44% in Minnesota and 43% in Chicago to 25% in Riverside/San Bernardino...High rates of current homelessness also reported in some areas, from 16% in Phoenix and 13% in Contra Costa County to 10% in Chicago and Alameda and 2% in Minnesota. [AHW, p.2.]

> Many people with AIDS are likely to lose their housing because of poverty, disability, and potential changes in welfare and support systems. 48% of Alameda (Count, California) respondents would lose their housing if they lost $100 a month in income. [AHW, p.3]
>
> Over 80% receive some type of federal or state assistance--primarily SSI and Medicaid. [AHW, p.3] 40% of Washington (State) respondents have needed housing or rental assistance and could not get it...The waiting list for Section 8 averages 3 - 5 years in each area; many times the list has not been open for years. [AHW, p. 4]
>
> As of October 31, 1995, over 311,000 persons were presumed living with AIDS. Up to 50% of persons living with HIV/AIDS are expected to need housing assistance of some kind during their lifetimes...We must plan for the housing needs of over 150,000 persons living with AIDS. [AHW, p. 4]

An estimate of the unmet housing needs of persons with AIDS on a national basis can be made by applying these survey illustrations to national statistics. Many of the over 300,000 persons living with AIDS are part of families in need of housing assistance, currently, or as noted in the AHW survey, at some time during their lifetimes. Increased needs in all communities can also be measured as the number of cases of AIDS and HIV infection continue to rise in every community. CDC reports that at the end of 1995, 513,486 cumulative cases of AIDS were reported in the nation, with 74,180 new cases reported in calendar year 1995 alone.

The appropriateness of assistance should also be addressed, particularly for persons experience other problems. Participants in the 1995 White House Conference on HIV and AIDS and others recommended that collaborative efforts be made by the Department of Housing and Urban Development and the Department of Health and Human Services to integrate funding streams for projects that address the needs of multiply-diagnosed clients. Participants noted that many communities lack resources within existing programs to assist these clients who are often among the hardest-to-serve population of persons living with HIV/AIDS. A survey of homeless providers presented in Priority: Home! The Federal Plan to Break the Cycle of Homelessness (issued in March, 1994 by HUD) found that among the top five priority areas consistently identified were mental health treatment services and substance abuse treatment services. The report recommended that communities be encouraged to "Effectively target mental health and housing resources to the most needy, such as homeless persons with mental illnesses or dual diagnoses" as part of developing more integrated systems of housing and services. The report also recommended that states and communities give some priority in existing and new funding to homeless persons with AIDS, including providing health care and other supportive services.

To support additional clients, communities also face greater needs in financing

housing efforts, such as increased costs from inflation and additional costs in responding to changing needs of clients, including assisting clients at higher levels-of-care as their health may deteriorate. Additional success with new therapies and medications has helped to increase the life span of persons living with AIDS, thereby increasing the period of time that housing assistance can benefit clients as well as the cost of care.

The following provides comments on the program descriptions:

A. Care and Services

Action Steps: [reworded] Award grants, both formula-based and competitively-selected grants, to support a broad range of housing and services to prevent homelessness of persons living with HIV/AIDS. Unmet need, see above.

B. Prevention

Response to question: HUD staff coordinated the meetings and other state and local agencies are responsible for the prevention program services. No budget is estimated, since the activities were carried out within existing HUD personnel resources.

C. Care and Services

Budget amounts represent the full program appropriation; no set-aside for persons with HIV is made. Unmet need, see above.

Objective 2 should be deleted as the entire Section 8 PWA set-aside was rescinded in FY 1995, along with other incremental voucher requests, and no action is planned in FY 1996.

Objectives 3-5 refer to HUD's homeless assistance programs and should be edited into one presentation given the redesign of these programs into a continuum of care system, as follows:

[replaces #3-5]

Objective 2: Assist Communities provide local comprehensive systems of housing assistance and related services for persons who are homeless by increasing the supply, accessibility and appropriateness of housing and related supportive service options to address the needs of persons who are homeless and living with HIV/AIDS.

Action Steps: Ensure the availability of funds to support community-wide efforts to comprehensively address the needs for emergency, transitional and permanent supportive housing for persons with HIV/AIDS.

Description: Continuum of Care Homeless Assistance, including the Supportive Housing Program, Shelter Plus Care program, and the Section 8 Moderate Rehabilitation for Single Room Occupancy Dwellings for Homeless Individuals program.

FY 95: $ 1.1 billion
FY 96: $ 675-925 million (estimate pending appropriations)

Populations served: Homeless persons and families, including persons with disabilities, such as persons living with HIV/AIDS.

Constituency Involvement. Communities participating in the development of coordinated and comprehensive systems of housing and care for persons who are homeless, include government agencies, nonprofit organizations, advocates, and consumers.

Unmet need. In 1995, HUD made the largest ever award of Federal funds to address the needs of persons who are homeless to communities and projects which are part of comprehensive and coordinated systems of housing and care. Although 881 projects were funded with the $904 million available in the competition, another 1,900 projects were not selected or funded due to the amount of funds available. These additional 1,500 projects requested about $2 billion in assistance. No measure of the unmet needs of HUD's other programs are made, although programs which support community economic development, the availability of affordable housing and reduce the rent burdens on clients through rental assistance may have considerable amounts of unmet need for persons living with HIV/AIDS.

D. Care and services (3 listings)

Constituencies: HUD program grantees, including State and local governments, housing authorities and finance agencies and non-profit organizations that develop, provide or coordinate services for persons receiving housing assistance, as well as advocates and consumers.

Funding--note that no additional program funds are requested as these activities are part of the functions of existing offices, such as the Office of HIV/AIDS Housing, Fair Housing and Equal Opportunities and other program offices.

[new, added]

E. Fair Housing and non-discrimination.

Goal: Increase the awareness of federal protection against discrimination on the basis of disability.

Objective: Ensure that HUD grantees, project sponsors, providers of housing assistance and related supportive services, advocates and current and potential residents are aware of the fair housing protection and remedies available to prevent and respond to discrimination on the basis of disability, including persons who are living with HIV/AIDS and their families.

Action Steps: Ensure the availability of educational materials, information and referral processes in cases of discrimination.

Description: Fair housing.

FY 95: (within current efforts)
FY 96: (within current efforts)

Populations served: Grantees, providers, advocates and consumers, including persons with disabilities, such as persons living with HIV/AIDS.

Constituency Involvement. Government agencies, nonprofit organizations, advocates, and consumers.

Unmet need. There may be a considerable need to inform and assist persons seeking protection against discrimination due to their HIV status.

If you have any questions on these comments and if I can be of additional help with drafting, please call me on (202) 708-0614 x 4620. Thank you for your efforts on this project.

JS? what's this? P

Agency: Social Security Administration

Goal: Provide information regarding benefits payable under the Social Security Act.

Objective: Provide information to people living with AIDS (PWAs) and to the medical community regarding eligibility requirements and changes in SSA programs as they apply to PWAs.

Action Steps: Inform PWAs about disability programs and eligibility requirements through mass mailings, electronic bulletin boards and community based organizations. Participation and exhibits at national conventions. Training of CBO on disability programs. Coordinate public information campaigns among Federal agencies and non-governmental organizations to disseminate information to more people more rapidly.

Descriptions: Public information campaigns

FY 95: NA
FY 96: NA

Populations Served: PWAs and their caregivers and advocates, the medical community and federal agencies

Constituency Involvement: PLWA, their caregivers and advocates; the medical community; national- and community-based AIDS organizations; coordinating federal agencies and SSA employees.

Unmet Need: Additional technical, clerical support to disseminate information to more people.

OPTIONAL FORM 99 (7-90)

FAX TRANSMITTAL # of pages ▶ 2

To Patsy Fleming	From Charlie Britton
Dept./Agency	Phone # 202-482-7108
Fax #	Fax #

NSN 7540-01-317-7368 5099-101 GENERAL SERVICES ADMINISTRATION

CARE AND SERVICES

Agency: Social Security Administration

Goal: Provide access to benefits payable under the Social Security Act.

Objective: Expedite and facilitate the processing of all disability claims, including those filed based on an allegation of HIV disease.

Action Steps: Process HIV claims under high priority status using procedures for processing claims where there is an indication of terminal illness.

Revise as necessary SSA's adjudicative policies based on dynamic nature of HIV disease.

Expedite claims processing by streamlining disability claims procedures and help AIDS service providers assist clients applying for SSI.

Descriptions: Disability and Social Insurance Programs and Outreach Demonstration Program (ODP).

FY 95: 1,005,000 plus 433,000 for ODP
FY 96: 1,200,000

Populations Served: People living with HIV eligible for ~~disability or~~ social security ~~insurance~~. Title II and/or Title XVI Benefits.

Constituency Involvement: People living with HIV and AIDS and their caregivers and advocates, the medical community, national AIDS organizations, SSA employees, coordinating federal agencies.

Unmet Need: Outreach programs now reach only four states. Additional funding would expand outreach project.

Revision Plan for National Strategy on HIV and AIDS

I. Timeline

May 7-11

X Finalize PF memo to CHR.
X Discuss with NIH concerns, schedule meeting prior to 5.17.
- Go back to departments and agencies for updated budget figures: FY95 actuals, FY96 updates, FY97 President's Budget request.

(Except for HHS, where budget figures will be obtained as part of final sign off.)

?? go back to HHS in advance with request for budget figures and RS's information re advances/where we are in course of epidemic. Could be folded into their comment re past planning and success with that. [have Richard ask for this information.

May 13 -17

X Meeting with NIH.
- Work on changes to text and appendices, specifically:
Incorporate HHS and other department and agency comments to text and appendices;

Incorporate recommendations from Adolescent Report;

Incorporate new Presidential Advisory Council recommendations; from SL

Update budget figures (FY95 actuals, FY96 updates, FY97 President's Budget request);

Incorporate findings from the coordinated research budget.

Update OVP efforts in the areas of vaccines, therapeutics, and microbicides.

Include more language on using the IDTF mechansism for resolving future issues. (Some issues are farther along than others, thereby guiding what groups will be involved and at what level. Important premise is that is important to be as inclusive as possible in developing solutions to these problems.) Council as mechanism.

Follow-up on items from 5.17 CHR meeting (OVP, harm reduction, NSC, efforts we have made in harm reduction). Change Medicaid language as per Jennifer Klein.

Reside in govt.

X Begin discussions on media plan.
X Meet with CHR on 5.17.96.

snapshot of where we are and where we need to go
IDTF/Council/Cty discuss flesh out steps ~ process collaborative hallmark of this approach. Admin's approach is interpretive does not

May 20 - 24

- Work on changes.

May 28 - 31

- Internal ONAP review. (5.29)
- Revise and send document to HHS for final review with ~~two~~ one week turnaround. (Due June ~~14~~ 7).-----
- Finalize media plan.

June 17 - 21

- Make final changes to text, appendices, budget tables.
- Meet with printing office.
- To printers on ~~6.24.96.~~ 6.17.96

Printers need at least 10 working days -- that would mean we could have pre-publication copies by around July 2nd. OR, have 'office-printed' copies available.

II. The Revisions --

■ **TEXT**

HHS comments
HHS notes
NLM plan
National Brease Cancer Action Plan -- example of natioanl, not federal plan
Role of treatment (HRSA, SAMSHA, IHS). Not hightlighted the way they should be. The main thrust of effort is the foundation for prevention efforts and to pull research subjects. Not presented they way it needs to be. (Goosby)
Text? Appendices?
*** how to address our response to their written and verbal comments?
What specific language changes
X Crosswalk of NIH submission
NIH changes as per 5.16 meeting
HHS official stuff: Appendices are a compendium -- Narrative is a starting point for a draft

HUD
Treasury
State
Education
Commerce
Labor
VA
Energy
Justice
OMB
SSA
Corporation for National Service
Peace Corp
OPM
ONDCP
USIA
USAID
EEOC
DOD

Terminology -- what do we want to call this -- for the cover?

Jane Silver.....

■ **APPENDICES**

HHS
HUD
Treasury
State
Education
Commerce
Labor
VA
Energy
Justice
OMB
SSA
Corporation for National Service
Peace Corp
OPM
ONDCP
USIA
USAID
EEOC
DOD

■ **BUDGET TABLES**

By substantive area
By agency

■ **EXECUTIVE SUMMARY**

✓Full PF letter
✓Full Goal of the NS
✓Abbreviated text from substantive sections
Appendices??
✓Budget Tables

1. Overall

95 96 97

Px
Rx
↓
TSOP

2. P
Px
Goal

① Agencies
② Internal/US

show Patricia what this looks like.

3. By Agency / Department

95 96 97

HHS
↓

• from Greg White 5
• Greg White natural history of funding.

typeset v. camera ready

■ **IN GENERAL .....**

- meet again with printing office re new timelines

*Look at the list of goals -- what stands out. What needs to be changed, emphasized, augemented, ...

who will keep track of what happens to the issues outlined in the plan????? ONAP? & Council

JS -- have a section of text that outlines issue resolution -- through the IDTF in concert with others .. such as the public sector companies and consumers, states, the Presidential Adivosry Council on HIV and AIDS, local entities. Office of National AIDS Policy, in collaboration with the PAC would be the nexus for resolution of these issues.

RS -- have specific items of accomplishments (i.e. we did this them ... discovered the virus ... found a test ... developed AZT ..)

Jeff's memo to CHR -- a starting point ... other language.

Dealing with the PAC

Prisoners -- language for Pat

Look at IHS HIV/AIDS Prevention Program
PF -- cure/vaccine, what about OIs
Check -- Are VA statements around confidentiality subject to problems, have there been breaches?

Meeting useful - presenting this as a snapshot.
& IDTF will resolve issues.
attempted to address your concerns.

Office of
National AIDS Policy

Correspondence Routing Slip

Tracking Number: G21616

Date Rcvd: 2-28-96

From: Stephen C. Joseph
The Assistant Secretary of Defense

Staff Action:

Reviewed By Jeff:_____ **Reviewed By: Patsy**_____

Assigned To: JS

RCVD:_____ **DONE:**_____

Recommendations/Instructions:

To Support Staff:_____

Date of Response:_____

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THE ASSISTANT SECRETARY OF DEFENSE

WASHINGTON, D. C. 20301-1200

HEALTH AFFAIRS

FEB 16 1996

Ms. Patsy Fleming
Director, Office of National AIDS Policy
Executive Office of the President
750 17th St. NW Suite 600
Washington, DC 20503

Dear Ms. Fleming:

I have reviewed the Draft of the National Strategy for HIV and AIDS. As you requested, the budget figures were checked and the necessary changes have been provided. Missing information on the attachments has also been provided. Attached are the updated papers on the following topics: Care and Services, Research, Prevention and International Activities.

If you have further questions, my points of contact are Colonel Salvatore Cirone, OASD(HA)CS (703-695-7116) or Colonel William Banchroft, USAMRMC (301-619-7567).

Thank you for the opportunity to participate in the National Strategy for HIV and AIDS.

Sincerely,

Stephen C. Joseph, M.D., M.P.H.

Attachments
As stated

CARE AND SERVICES

Agency: Department of Defense

Goal: Provide state-of-the-art patient-centered comprehensive care for all eligible service members throughout the asymptomatic and symptomatic phases of HIV and AIDS.

Objective: Provide immediate evaluation and continuity of care for service members who become HIV positive.

Through contact tracing, identify persons at risk and provide consultation and evaluation. Refer to care as appropriate.

Provide continuation of employment until no longer physically fit for duty.

Action Steps: Conduct periodic screening of active duty personnel;

For HIV positive personnel, provide comprehensive evaluation, treatment, and care;

Restrict assignment to continental U.S., Alaska, Hawaii, or Puerto Rico to assure continuity of medical care; and

Educate health care staff on best clinical practice for persons living with HIV.

Descriptions: Comprehensive state-of-the-art clinical care.

FY 95: ~~$2,680,000~~ $2,000,000 to $3,000,000
FY 96: ~~$2,680,000~~ $2,000,000 to $3,000,000

Populations Served: HIV positive active duty personnel.

Constituency Involvement: ???

Unmet Need: ~~???~~ None.

RESEARCH

Agency: Department of Defense

Goal: Carry out state-of-the-art research on the prevention and treatment of HIV infection to promote medical readiness in U.S. military forces.

Objective: Support the development of a safe and effective HIV vaccine.

Support the development of new biochemical and genetic strategies to slow HIV disease progression

Support natural history studies for the purpose of evaluating the efficacy of intervention strategies.

Action Steps: Define the global molecular epidemiology of HIV to assist with candidate vaccine selection;

Explore novel vaccine technologies;

Conduct vaccine trials in endemic areas;

Assess the immune response and efficacy of vaccine candidates;

Evaluate potential therapies for treatment of HIV infection and potential for immune reconstitution;

Evaluate prevalence of drug resistance, develop rapid genetic assay for resistant mutants, and methods for genetic targeting of novel therapies *in vivo*;

Participate in national surveillance of AZT resistance;

Develop a comprehensive panel of immunologic, virologic, and functional parameters for management of HIV infection; and

Support natural history studies and specimen repositories.

Descriptions: Vaccine, therapeutic, and epidemiological research.**

FY 95: ~~$28,500,000~~ $37,000,000
FY 96: ~~$31,560,000~~ $26,600,000

Populations Served: Active duty personnel.

Constituency Involvement: Clinicians, researchers, and active duty personnel.

Unmet Need: Increased resources would permit more aggressive research on promising ~~therapies~~ and vaccine candidates.

**Vaccine design, development and testing in the U.S. and overseas locations; epidemiologic studies of vaccine field sites; reduction or conclusion of drug treatment and behavior studies.

PREVENTION

Agency: Department of Defense

Goal: Preservation of an effective fighting force through prevention of HIV infection.

Objective 1: Prevent HIV infection in service members.

Reduce the number of new active duty HIV infection by 20 percent by 1997. (What is the baseline figure for this reduction?)
Answer: 1995 baseline figure is 204 for all Services.

Action Steps: Provide basic information on HIV transmission and risk reduction for new recruits, civilian work force members, and officers;

Require education and general military training on methods of transmission and approaches for avoiding transmission, including barrier methods, avoidance of intravenous drug use, and use of universal precautions;

Provide training for personnel, instructors, and peer educators; and

Support train the trainer courses to develop multidisciplinary teams from medical, dental, nursing, and public health corps for promoting HIV and AIDS education.

Objective 2: Ensure safety of the Armed Services Blood Program (Office) (ASBPO)

Action Steps: Advise service personnel with serologic evidence of HIV infection or repeated ELISA reactivity, but Western Blot negative or indeterminate, to refrain from donating blood.

Employ ASBPO "Look Back Program" to trace contacts of identified positive donors who serconvert after blood donation -- trace and contact blood recipients.

FY 95: ~~$245,000~~ Approximately $500,000.
FY 96: ~~$245,000~~ Approximately $500,000.

Populations Served: Active duty service members and their eligible family members, health care providers and those at risk of exposure to body fluids, and recipients of ASBPO blood products.

Constituency Involvement: Active duty force, affiliated civilian workforce, and the health care and public health communities.

Unmet Need: ~~None?~~ Answer: None.

INTERNATIONAL ACTIVITIES

Agency: Department of Defense

Goal: Support leadership in the international community by sharing research methodologies and findings, observing host nation requirements for HIV testing and reporting, and supporting research at international sites with high prevalence or incidence of HIV and AIDS.

Objective: Participate in global surveillance initiatives and maintain current knowledge of host nation HIV screening and reporting requirements.

Action Steps: Determine the prevalence of HIV initiative, infections, and genotypes in geographic areas of military activity.

Coordinate with Department of State.

Descriptions: International efforts.**

FY 95: ~~???~~ $1,500,000
FY 96: ~~???~~ $1,500,000

Populations Served: ~~???~~ Foreign National and active duty U.S. military.

Constituent Involvement: ~~???~~ Active duty military and foreign service nationals of DoD overseas laboratories.

Unmet Need: ~~???~~ None.

**Study geographic distribution of genotypes at DoD overseas laboratories. Work supports basic research on diagnostic tests and vaccines.

UNITED STATES DEPARTMENT OF EDUCATION

OFFICE OF ELEMENTARY AND SECONDARY EDUCATION

March 6, 1996

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

From : William Modzeleski
Director, Safe and Drug Free Schools Program

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

As requested, we have reviewed the Draft National Strategy for HIV and AIDS and have the following comments:

- A final FY 1996 budget for the Department of Education has not yet been passed by Congress therefore no budget figures are available to include in the Plan. It should be further noted, that if ED receives significant reductions in those programs that deal with HIV/AIDs the Plan may need to be modified to reflect the decrease. For example, the current House and Senate proposals (not the CR), call for complete elimination of all discretionary grant funds for the Safe and Drug Free Schools Program. If this occurs, or if there are substantial decreases in funding, we will not be able to prepare a publication on the relationship between HIV/AIDS and drug use.

- The plan included in the appendix is considerably different than the one submitted last year, are we to assume that agencies are to concentrate their efforts on what is included in this draft?

Comments regarding the plan included in the Appendix follow.

- In the Department of Education appendix, Objective 1, Action Step #2, should read: Include information related to school-based comprehensive health programs (ED funded) in the Comprehensive Health Information Database (HHS).

  Names of programs that would be shared with HHS were included in Attachment A of our original submission.

  Constituency Involvement: Majority of ED programs are developed at local level and therefore there is little involvement of constituency groups at the Federal level.

- Objective #2, It is uncertain whether any publications will

be developed. Our original submission was developed prior to our current budget. It is unlikely that we will have discretionary funds to develop any new publications.

No budget figures are available for 1996.

Populations served: the write up is accurate.

If there are any questions regarding our comments please contact me. My direct line is 260-1856.

Office of
National AIDS Policy

Correspondence Routing Slip

Tracking Number: G2580

Date Rcvd: 2-20-96

From: Rafael Borras,
Dept. of Commerce

Staff Action:

Reviewed By Jeff:_____ **Reviewed By: Patsy**_____

Assigned To: JS

RCVD:_____ **DONE:**_____

Recommendations/Instructions:

To Support Staff:_____

Date of Response:_____

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UNITED STATES DEPARTMENT OF COMMERCE
Chief Financial Officer
Assistant Secretary for Administration
Washington, D.C. 20230

FEB 14 1996

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

Dear Ms. Fleming:

We have reviewed the draft National Strategy for HIV and AIDS. In our section of the appendix, the redlined information should be updated as follows:

- The future of the Advanced Technology Program (ATP) is uncertain. ATP, like the rest of the Department, is operating under a continuing resolution until March 15, 1996. Information and updates on the status of ATP are now available on the World Wide Web at http:/www.atp.nist.gov.

- With respect to constituency involvement, the Department supports the need for partnerships between the private and public sectors. In the text of the draft report you mention the need for such partnerships in developing a vaccine and medications. We believe that this concept can be expanded to other research activities as well, and that the Department of Commerce, with its vital ties to the global business community, can encourage such innovations.

- As you noted in the draft report, research is an investment in America's future. Our current need is to increase support for valuable programs such as ATP and the Patent and Trademark Office's innovative AIDS-related patent database.

Thank you for the opportunity to review the National Strategy Report. This document outlines a cohesive, focused approach and will serve as a valuable tool in the fight against HIV and AIDS.

Sincerely,

Rafael Borras
Deputy Assistant Secretary
for Administration

FAX COVER SHEET

Date: February 15, 1996

To: Jane Sanville

Fax Number: (202) 632-1096

From: Linda Hess for Rafael Borras, U.S. Department of Commerce

Fax Number: 202/482-3592 Telephone Number: 202/482-4951

Total number of pages including cover: 2

Original document will be mailed today.

UNITED STATES DEPARTMENT OF COMMERCE
Chief Financial Officer
Assistant Secretary for Administration
Washington, D.C. 20230

FEB 14 1996

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

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- As you noted in the draft report, research is an investment in America's future. Our current need is to increase support for valuable programs such as ATP and the Patent and Trademark Office's innovative AIDS-related patent database.

Thank you for the opportunity to review the National Strategy Report. This document outlines a cohesive, focused approach and will serve as a valuable tool in the fight against HIV and AIDS.

Sincerely,

Rafael Borras
Deputy Assistant Secretary
for Administration

United States Department of State

Bureau of Oceans and International Environmental and Scientific Affairs

Washington, D.C. 20520

March 1, 1996

Ms. Patricia S. Fleming
Director, Office of National AIDS Policy
Executive Office of the President

Dear Patsy:

Thank you for the opportunity to comment on the draft National Strategy for HIV and AIDS. The document is comprehensive and includes an accurate description of the efforts underway by several agencies to ensure that the AIDS pandemic is addressed on a global scale. The document refers to the interagency effort that led to the development of an International Strategy on HIV and AIDS, and includes the actions that are most critical to move this strategy forward.

Under the resources section of the document, you seek clarification of several points. With regard to funding for the UNAIDS program, you should direct questions in this area to USAID. More generally, you ask about the capacity of the State Department to staff the international actions identified in the international strategy. While the OES Bureau continues to serve a coordinating role in implementing the strategy, practically speaking we lack the personnel necessary to move these actions forward in a timely fashion. Given the current budget and personnel constraints within our Department, I do not foresee a near-term change in this situation. I consider this to be a major obstacle to progress in working with our foreign counterparts to address the pandemic.

We will be seeking every possible means within our existing resources to fulfill the goals of the international strategy; however, your concerns about staffing as expressed in your draft document are indeed valid. I welcome your thoughts on ways to address this problem.

Sincerely yours,

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

John Rogers - OPM → no comment / 2.13.96
Nat'l plan!

May 24, 1996

MEMORANDUM FOR INTERDEPARTMENTAL TASK FORCE ON HIV/AIDS,
OFFICE OF PERSONNEL MANAGEMENT

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

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

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

This past February, IDTF members reviewed the draft and provided comment. We are in the final stages of revising the document as informed by this review, and, updating budget figures.

The table below reflects the budget levels in your submission. Please update the table to reflect current figures; these budget figures will be cross-checked with OMB figures. Attached is the OPM Aappendix you submitted to assist you in your review.

Area	**Goal/Objective**	**FY 95 Actuals**	**FY 96**	**FY 97 President's Budget**
Care and Services	Goal: Implement and improve workplace policies and employee benefits.			
	Objective 1: Implement and improve workplace guidelines.	$20,000	$15,000	
	Objective 2: Improve life insurance benefits programs.	None	None	

Comments are due back to the Office of National AIDS Policy **BY NO LATER THAN MAY 31, 1996.** If you have any questions please call Jane Sanville at (202) 632-1090.

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

Attachment: Office of Personnel Management Appendix for National Strategy on HIV and AIDS

CARE AND SERVICES

Agency: Office of Personnel Management

Goal: Implement and improve workplace policies and employee benefits.

Objective 1: Implement and improve workplace guidelines.

Action Steps: Publish and distribute OPM's "HIV/AIDS Policy Guidelines".

Publish and distribute OPM personnel manuals on related HIV/AIDS issues, such as information on accommodations for employees who are HIV positive and on educational resources.

Descriptions: Policy development.

FY 95: $20,000
FY 96: $15,000
FY 97:

Populations Served: Federal agencies and employees, including labor organizations.

Constituency Involvement: Federal agencies and employees, including labor organizations.

Unmet Need: None.

Objective 2: Improve life insurance benefits programs.

Action Steps: Distribute guidance on "living benefits" insurance benefits.

Develop and distribute guidance on viatical settlements.

Descriptions: Insurance programs.

FY 95: None.
FY 96: None.
FY 97:

Populations Served: Federal agencies and employees and retirees covered by the Federal Employees Group Life Insurance Program.

Constituent Involvement: Federal agencies and employees and retirees covered by the Federal Employees Group Life Insurance Program.

Unmet Need: None.

United States Department of State

Bureau of Oceans and International Environmental and Scientific Affairs

Washington, D.C. 20520

March 1, 1996

Kathoma - 3.18.96

Here are USAID's and State's Responses to the National Strategy. USAID has one page missing - people tracking it down. State's response is cryptic to me - I would appreciate your help in interpreting it.

Thanks - Anne

comment on the draft National Strategy for HIV ive and includes an accurate description of the nsure that the AIDS pandemic is addressed on a interagency effort that led to the development of DS, and includes the actions that are most critical

document, you seek clarification of several NAIDS program, you should direct questions in ask about the capacity of the State Department d in the international strategy. While the OES role in implementing the strategy, practically to move these actions forward in a timely rsonnel constraints within our Department, I do uation. I consider this to be a major obstacle to nterparts to address the pandemic.

We will be seeking every possible means within our existing resources to fulfill the goals of the international strategy; however, your concerns about staffing as expressed in your draft document are indeed valid. I welcome your thoughts on ways to address this problem.

Sincerely yours,

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

Office of
National AIDS Policy

Correspondence Routing Slip

Tracking Number: G 2661

Date Rcvd: 3-7-96

From: Anne Solomon

Staff Action:

Reviewed By Jeff:_____ **Reviewed By: Patsy**_____

Assigned To: JS

RCVD:_____ **DONE:**_____

Recommendations/Instructions:

To Support Staff:_____

Date of Response:_____

n:\corresli

United States Department of State

Bureau of Oceans and International Environmental and Scientific Affairs

Washington, D.C. 20520

March 1, 1996

Ms. Patricia S. Fleming
Director, Office of National AIDS Policy
Executive Office of the President

Dear Patsy:

Thank you for the opportunity to comment on the draft National Strategy for HIV and AIDS. The document is comprehensive and includes an accurate description of the efforts underway by several agencies to ensure that the AIDS pandemic is addressed on a global scale. The document refers to the interagency effort that led to the development of an International Strategy on HIV and AIDS, and includes the actions that are most critical to move this strategy forward.

Under the resources section of the document, you seek clarification of several points. With regard to funding for the UNAIDS program, you should direct questions in this area to USAID. More generally, you ask about the capacity of the State Department to staff the international actions identified in the international strategy. While the OES Bureau continues to serve a coordinating role in implementing the strategy, practically speaking we lack the personnel necessary to move these actions forward in a timely fashion. Given the current budget and personnel constraints within our Department, I do not foresee a near-term change in this situation. I consider this to be a major obstacle to progress in working with our foreign counterparts to address the pandemic.

We will be seeking every possible means within our existing resources to fulfill the goals of the international strategy; however, your concerns about staffing as expressed in your draft document are indeed valid. I welcome your thoughts on ways to address this problem.

Sincerely yours,

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

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Office of the Secretary

Assistant Secretary for Health
Office of Public Health and Science
Washington D.C. 20201

APR 10 1996

NOTE TO JEFF LEVY

SUBJECT: Comments on the Draft National Strategy for HIV/AIDS

This follows the meeting last Wednesday with you, Jane Sanville and representatives from the Department's Staff Divisions wherein we discussed your preliminary draft National Strategy for HIV/AIDS. The consensus at the meeting was that the preliminary draft document in its present form should not be considered a draft strategy or plan for HIV/AIDS. Specifically our major concerns are that discussion of specific objectives in the draft be viewed as a compendium of current program activities underway in the Federal government and that the narrative portion of the draft be the starting point from which an actual national strategy could evolve.

Specifically, the following broad concerns need to be considered in formulating a national strategy for HIV/AIDS:

- Involvement of State and local entities and the private sector (business, health, education/academic, research) interests to insure that the strategy is representative of national views and responsibilities. This is essential in insuring a strategy that encompasses more than just Federal government participation.

- The strategy should be built upon previous plans and activities to address HIV/AIDS, both in the Federal (including Congressional) and non-Federal sectors. Progress in combatting the disease as a result of previous efforts should be cited.

- The development of a strategy to address HIV/AIDS should be crafted within a defined context of the current scope of the disease. The challenge should be articulated in terms of: the changing nature of HIV/AIDS and why its effects are different today than 10 years ago, and 5 years ago; the demography of the disease and the populations it is now affecting as

compared to past years; new research discoveries that have taken place in recent years and months that are changing the direction of HIV/AIDS treatment and prevention; other, societal changes that are influencing and impacting the ways we address issues of health care, access and cost in our nation (for example: the move to decentralize the role of the Federal government and place more responsibilities at State levels, shrinking Federal, State and local resources, the movement to managed care systems); and the impact these changes may have on our continued efforts to insure care and services for people with HIV/AIDS and to strengthen prevention efforts.

o As a basis for developing the strategy, working groups comprised of Federal and non-Federal participants should identify and delineate met and unmet needs and craft a strategy that moves the nation toward a comprehensive solution.

Attached are technical comments from various reviewers within the Department. We look forward to reviewing the revised document.

Eric P. Goosby, M.D.

Attachments

Draft National Strategy for HIV and AIDS

Comments

Overall

- The document should contain a **Preface** that describes: why this plan was developed (the need for it at this time), for whom is it intended (who is the audience?); what is its purpose/intended use; who (what individuals or organizations) participated in preparing it and reviewing it. These are important points to address at the beginning of the document in order to provide a context for the plan and the actions it recommends.

  Note: We would recommend that part of the developmental process for a "national" plan include a method for insuring non-Federal review by a variety of known experts in the specific areas addressed in order to achieve consensus on the importance of issues and the best manner in which to resolve them.

- The "Letter" from the National Director of ONAP should be revised into a **Message from the National Director of ONAP** of no more than one and one half pages that clearly articulates the urgency of the HIV/AIDS crisis, calls for a unified national approach to addressing it, provides an overview of the urgent priorities that lead to developing this plan, and ends with a statement of vision in how this plan can be instrumental in combatting this disease.

- Additionally, the document should contain an **Executive Summary** to highlight the goals and associated areas for progress, and to summarize the key recommendations of this plan. This Executive Summary would be very useful in synthesizing the key issues presented in the more voluminous plan.

- We suggest that a professional editor review the whole document to provide consistency of terms and to standardize the language so that the document flows as if written by one entity.

- The document needs to be double checked for accuracy of all data, budget figures, and cost figures, presented throughout.

Discussion of Issues

- Page 5. In discussions of the Scope of the disease and the public health threat, some historical perspective is called for in order to illustrate the growing problem HIV/AIDS continues to present after 15 years.

- Page 7 - Discussions of "The Social Impact" of this disease should be strengthened. Specifically this section needs to be expanded to include specific indications of the impact in areas of cost to the Nation in terms of lost lives/productivity and cost issues associated with treatment and care for those infected with HIV disease.

- Page 9. The list of three goals does not match the order of the ensuing "areas for progress" on page 10. A specific goal for substance abuse should be included in the list of goals.

- Page 10. The "Challenge of the HIV Epidemic," needs to be updated. Statements such as "... we now know how it (HIV) is transmitted ..." and "... we have a test to diagnose infected persons and to protect the blood supply," contain information that is over a decade old and widely known. (The HIV antibody test has been in use since 1984.)

  The discussion here should embrace the challenge of the epidemic as different than that which was experienced a decade ago. This is best seen in the changing nature of HIV and AIDS: more young women are becoming infected, minority populations are at especially high risk, the geographic diversity of this disease has widened, therefore its impact on the country has increased. What are the current and future implications of this for the country? How do we move to address the needs presented by this ever expanding, more diverse disease in an environment of critically shrinking Federal, State and local resources caused in part by changing cultural attitudes that define government as small not big, decentralized and limited in its authority to provide reimbursement for health care, treatment and services for needy populations, such as people with HIV/AIDS?

- Page 12, "Overview of Federal Efforts." This section should include some reference to the level of past efforts to combat HIV/AIDS (including in general amounts the money that has been spent on Federal programs over the past 15 years.) This section should also include Congressional legislative efforts (Ryan White CARE Act, Americans with Disabilities Act, etc.) to assist people with HIV and AIDS and their families.

  In this section, discussions of how this "report" is organized should be moved to the front of the document, perhaps as part of a preface section that we recommend should be included (see first page of comments.)

- Page 14 - 22, "Prevention." The Prevention section lacks a clearly stated concept of targeting high-risk populations. Identifying HIV positive patients in these high-risk populations and bringing them into a continuum of care and support services is essential for maximizing our ability to effectively impact on the spread of the HIV epidemic. The role of protease inhibitor combination drug therapy on primary prevention is not addressed and needs to be.

- Page 16, third paragraph. The role of surveillance as a link to epidemiologic data in order to target high risk populations is eluded to but not discussed in the context of program activity (there is a need to address how to do this, who should do it, etc.)

- Page 18, second paragraph - a sentence needs to be added to state that more research is needed in recidivism and strategies to minimize.

- Page 19, "Community Involvement," second paragraph. A point needs to be made with regard to the lack of accountability in the allocation decisions. The States make the final allocation decision, the Planning Councils' recommendation are only recommendations.

- Page 21, fourth paragraph, first line: "While the data strongly support the effectiveness of needle exchange programs in preventing the spread of infection ..." This statement does not represent DHHS or Administration policy.

- Page 29, "Public-Private Partnerships." The Office of HIV/AIDS Policy in DHHS assists the ASH in coordinating the development of standards of care across the public health operating divisions in the Department (NIH, CDC, HRSA, SAMHSA, and AHCPR.) This includes acting in a liaison capacity with the private sector, the pharmaceutical industry and HMOs.

- Page 32, "Opportunities for Progress." A central challenge to provision of care and services for HIV/AIDS patients and their families is the current public debate regarding the redefinition of the Federal role in providing reimbursement and the growing support for these responsibilities to be remanded to the States. Important questions need to be examined such as: will the programs continue? What are the implications for people with HIV/AIDS and their families? Are there current studies on what the impact of this will be on affected individuals, families, States and the country as a whole?

  Another challenge is the concurrent move to managed care and the implications this will have for HIV/AIDS patients, particularly as Federal reimbursement/support systems shrink and health care becomes more defined as profit based. While the answers are as yet not fully known, these questions or similar concerns should be raised in any discussion of provision of care and services to people with HIV/AIDS.

- Page 32, add - Other sources of primary care supported by the Federal government are: Department of Defense (DoD) which cares for 1,094 HIV/AIDS positive patients; Department of Veterans Affairs which cares for 17,000 HIV/AIDS patients in VA hospitals and clinics; and the Indian Health Service/DHHS which provides health care for 1,000 known HIV infected Native Americans and Alaska Natives (NA/AN) and 300 NA/AN people with AIDS. Additionally, the Department of Justice's Bureau of Prisons provides care for HIV/AIDS infected persons in the Federal prisons (page 34).

- Page 33, 4th. paragraph, Add - " Linking an HIV positive person with care also provides an opportunity to impact on primary prevention. Infectivity appears to be directly proportional to decreasing viral load. Decreasing viral load appears to result in decreasing infectivity.

The role of nucleosides and the new protease inhibitor combination drug therapy is yet to be defined, but is very promising."

- Page 35, add - "The DHHS needs to coordinate across agencies to maximize coordination attempts at the local level."

- Page 37, add - "The Office of HIV/AIDS (OHAP) DHHS has established joint projects with the Ministry of Health in Canada on palliative care and rehabilitation of HIV infected people.

- Page 39, second paragraph, information dissemination, add - "At DHHS, in a joint collaborative effort, OHAP and HRSA support and direct the International HIV/AIDS Clinical Conference Call series which disseminates critical, state-of-the-art information on treatment for HIV/AIDS patients to primary care providers via live world-wide audio teleconferencing.

  OHAP is also coordinating implementation of the protease inhibitor combination drug therapy in DHHS health programs. Additionally, OHAP is the lead organization for the development of standards of care associated with this new therapeutic intervention.

- Page 40, "Coordination of Federal Activities," first paragraph. A statement should be inserted that clarifies that OHAP is the lead office for coordinating the HIV/AIDS activities in the public health operating divisions of the DHHS.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Office of the Secretary

Washington, D.C. 20201

MAR 5 1996

TO: Claudia Cooley
Executive Secretary

FROM: PBE Peter B. Edelman

SUBJECT: Draft *National Strategy for HIV and AIDS*

Because of the abbreviated time frame for reviewing this lengthy document and detailed appendix, many HHS agencies have not had sufficient opportunity to review the scientific and technical accuracy of the report, substantive areas covered (including some that are not without controversy such as needle and syringe exchange programs), and the research and program priorities that have been identified for the Nation as a whole and individual agencies. At this point, we understand that some general concerns have already been raised about the content and structure of this report and that additional time is required to address these issues. We share this concern and would appreciate receiving copies of the agencies' comments.

Although we do not have specific comments at this time, we did note a conspicuous disparity in the individual agencies' submissions regarding their HIV/AIDS program activities (Appendix). Agencies should be asked to provide additional detail or descriptive information about their program activities and priorities. Additionally, in the discussion of needle exchange programs on page 21, the first sentence of the last paragraph seems inconsistent with the Administration's current position. To further clarify the last sentence of this paragraph, there may need to be some mention of the current restriction on the use of Federal funds in supporting needle exchange programs. In short, this report is expected to make an important contribution to national HIV/AIDS policy making and thus merits careful and thoughtful agency review.

cc: Glen Harelson

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Health Resources and
Services Administration
Rockville MD 20857

FEB 23 1996

NOTE TO PATSY FLEMING

SUBJECT: Comments on National Strategies for HIV/AIDS

This is to congratulate you and your office on the development of this important document. I have comments below which I hope will be helpful:

page 9, bullet 3:	should read HIV/AIDS rather than AIDS
page 10, paragraph 2, line 3:	strike "very different" and replace with "increasingly more complex"
page 10, paragraph 3, line 5:	strike "receive quality health care" and replace with "benefit from scientific advances capable of prolonging and increasing quality of their lives."
page 11, paragraph 2, line 6:	strike the word "treatment" (as it stands, it implies that there is no treatment for AIDS.)
page 12, paragraph 1, line 13:	add "academic institutions, private foundations, health care institutions" after "State and local governments" and before "and community based organizations."
page 15, paragraph 1, line 19:	add at end of paragraph this sentence: "HRSA also has undertaken special initiatives designed to reduce perinatal transmission of HIV and has promoted primary prevention through the training of health professionals in the AIDS Education and Training Centers Program.
page 20, paragraph 3:	In addition to alcohol, cocaine use linked with sex-for-drugs is an important factor.
page 20, paragraph 5:	This would be a good place to stress the importance of maintenance of traditional (directly observed therapy) public health approaches to TB surveillance, prevention, and treatment.

page 31, paragraph 1:	Insert after the first sentence: "Many Americans are uninsured by either public or private means. Additionally, poverty, racism, homophobia, geography, and other barriers create access problems beyond those related to lack of insurance. These barriers to access are exacerbated in the context of HIV/AIDS. For individuals with health insurance, maintaining adequate coverage...." Strike "For many of these persons, maintaining..."
page 31, paragraph 4, line 5:	strike " to fill certain gaps in coverage for people living with HIV/AIDS." and replace with "fill gaps in coverage and build systems of care to create access to health care for people living with HIV/AIDS."
page 31, paragraph 4, line 11:	IIIb not III
page 32, paragraph 1:	add as a final sentence: "HRSA also supports professional education so that there will be an adequate supply of providers knowledgeable in HIV/AIDS treatment."
page 33, paragraph 2:	rather than "counseling and testing" you might consider using the broader term "primary prevention."
page 35, paragraph 3:	strike "medical schools", add "professional schools"
page 37, paragraph 1:	the importance of activities supporting treatment of STDs, particularly genital ulcer disease, in prevention of transmission of HIV, is extremely important in developing countries.
page 38, paragraph 2, line 13:	strike the word "identifying" (identifying what?)
page 39, paragraph 1, line 6:	strike "caring for" replace with "assessing risk, prevention, and caring for"
page 39, paragraph 2, line 22:	strike the last sentence. Replace with, "The Health Resources and Services Administration has developed guidances for its CARE Act grantees, supports international clinical conference calls on current topics, funds an AIDS warmline which responds to questions from clinicians across the country, and directs a nationwide system of AIDS Education and Training Centers which provide State

of the art HIV clinical information to health care providers. Additionally, HRSA supports a number of conferences featuring clinical updates and information."

page 40, paragraph 2, line 3: strike phrase, "study indicated that primary care physicians miss..." and replace with "study indicated that many primary care physicians miss..."

page 41, paragraph 2, line 7: do you want to add "businesses, churches, schools" etc. ?

page 42, paragraph 2, line 5: what type of "testing programs" ? Also the last sentence is problematic at the moment.

The following comments refer to the appendix:

In general, do you want to list the President's budget (in contrast to the Congressional approach)? Also, in listing constituency groups, it would read better to always list PLWAs first.

Page 3 (Care and Services): paragraph 9: The issue of formularies is tricky, a good idea, but one that is going to require some thought as to how we can do this without creating a system that subsidizes Medicaid and private managed care formularies.

paragraph 12: if this refers to the WIN projects, we now have 10 (3 funded with SPNS dollars.)

paragraph 16: indicators not indicator

Page 4 Paragraph 3: In addition to these broad based efforts, HRSA also supports a variety of focused initiatives such as an adolescent research and clinical network and a cooperative.....

Page 4 Insert:

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

President's Budget

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

paragraph 5: constituents are also represented on the HRSA AIDS Advisory Committee

paragraph 8: add, "working with NIMH, SAMSHA and other relevant agencies to insure access to mental health and substance abuse services" strike "to provide needed services."

Page 5

Add this paragraph:

From the point of view of the front line provider who may receive funding from several Federal agencies, a need for improved coordination within agencies and between agencies is often apparent. In addition, for example, to the lack of adequate resources for technical assistance and evaluation, there is also a need for improved planning and coordination of these activities between the various CARE activities and between Federal agencies.

Thanks again for the opportunity to review this document.

Sincerely,

Shirley B Gordon

Joseph F. O'Neill, M.D., M.P.H.
Associate Administrator for AIDS

General Comments

- It would be helpful if an "introduction section" could be added to the National Strategy for HIV and AIDS (NSHA) that briefly explains what Federal Departments and independent agencies, and other groups outside the government were involved in the development of this strategy.

- There is a lack of consistency of terminology throughout the NSHA. This is the plan of the Executive Branch of the Federal Government, which includes a number of departments and agencies. The cover memorandum from the Director states that "I believe this document builds on this consensus and articulates the goals and objectives of the entire Federal Government." This may be stated as the "Executive Branch of the Federal Government" since it does not include any Congressional or legislative branch collaboration.

- Before the final NSHA is published, a version with all of the appendices should be circulated for review and final clearance.

Additional Comments

Page 2, paragraph 2, line 2 "This is the first time a government-wide national plan for the United States has been developed for fighting HIV." There have been plans developed earlier in the epidemic (see page 8, paragraph 3, line 1). It would be helpful, and more accurate, to explain as early in the document as possible why this "government-wide national plan" is different than previous plans developed at Coolfont, Charlottesville, and the PHS Strategic Plan.

Page 2, paragraph 5, line 1 "The purpose of this comprehensive national strategy is to set forth overarching national goals and priorities for 1996 in charting our course for combatting the epidemic of HIV and AIDS." It is not clear if the national strategy included collaboration with outside groups. Also, is it the calendar year 1996 or the fiscal year 1996?

Page 3, paragraph 2, line 13 "Medicare and Medicaid is being threatened by funding changes" could be edited to read "threatened by fundamental (or basic) programmatic changes and reductions in funding."

Page 3, paragraph 4, line 1 "The epidemic of HIV and AIDS threatens the economic progress of many countries around the world." What follows in the text is a short discussion of the United States only.

Page 6, paragraph 1, line 1 Footnote 1 (or 1a) - "It is anticipated that this trend could be reversed with the implementation of the PHS recommendations for the administration of AZT to women during pregnancy and to their infants after birth." Since taking AZT is an option, we may need to insert "potentially" before the word could. CDC's guidelines (July 1995) state "To reverse these trends (HIV infection increasing among women and thus becoming a leading cause of death among young children) HIV education and services for prevention and health care must be made available to all women."

Page 7, paragraph 2, line 6 "And unlike other persons with infectious diseases, many persons living with HIV to have been the target of violence, rejected by their families, and suffered discrimination based on their HIV status."
The discrimination is also based on sexual orientation. Also, strike the "to" after the word "HIV" in that sentence.

page 7, paragraph 3, line 1 In this context, "anytime" should be two words, "any time"

Page 8, paragraph 1, line 4 "To ensure efficient use of Federal, State, local, and private resources, it is imperative to plan and coordinate government-wide efforts." This statement is not clear - how does this strategy ensure efficient use of private and local resources?

Page 8, paragraph 2, line 1 "This is the first time a government-wide national strategy for HIV and AIDS for the United States has been developed." See earlier comments (above) about consistency in the name of the plan and which directly reflects whic Federal agencies or other organizations collaborated in its content. In addition, the text should include how State and local governments were involved in its formulation.

Page 8, paragraph 3, line 2 "To date, planning has been primarily focused in the Public Health Service as evidenced by a series of documents such as..." These previous efforts have been

very briefly mentioned in the document. It should be noted and included that the Department of Health and Human Services delegated the responsibility to the Public Health Service to lead the effort to halt the AIDS epidemic. For readers unfamiliar with the Public Health Service, it may be helpful to include a footnote that it includes eight agencies, with the following seven NIH, FDA, CDC, HRSA, SAMHSA, AHCPR, IHS working on various aspects of the HIV/AIDS epidemic. The PHS is the lead Federal agency for health related issues. Also, while the Surgeon General's report on AIDS was not "technically" a plan, it is a benchmark of previous efforts. The public or the Congress may inquire of the NSHA document "How will the "National Strategy" plan be different from or have better results than previous efforts?"

Page 8, paragraph 3, line 9 "Recommendations have also been issued from a number of groups, including the National Commission on AIDS in addition to significant planning efforts on the part of individual agencies." The text, or a footnote, could be included to explain there were Congressionally legislated Commissions with Cabinet officers of different Executive Departments serving on these Commissions, including the Secretary of HHS. The HHS received the recommendations of these Commissions because of its health care mission.

Page 9, paragraph 1, line 15 "The insights provided by a number of groups including the National Commission on AIDS, the Institute of Medicine and National Research Council, the General Accounting Office, and the Office of Technology Assessment have also been helpful." It is not clear what insights were received. Since the Office of Technology Assessment has been eliminated by the current Congress, it may be better to refer to either specific reports or formal/informal collaborations these various entities have produced on HIV/AIDS or expert advice that they have offered.

Page 9, paragraph 1, line 18 "Therefore, the expertise and experience of those who work closely with communities, clinicians, researchers, service and research organizations, and infected persons is reflected in these goals and opportunities for progress." It appears from this statement that the "input" was "indirect" from these groups. Since this is

a Federal government document, it is anticipated that questions on the exact nature of the collaboration with groups and State and local governments will arise.

Page 9, bullet 3 — "Ensure appropriate care for and ethical treatment of persons with AIDS." It is not clear what "ethical" treatment involves in this context. Also, it should read "persons living with HIV/AIDS."

Page 9, paragraph 3, line 6 — "There was also a common sense that these challenges also represented opportunities for progress --..." Should "common sense" instead read "common objective" or "common goal?"

Page 10, paragraph 3, line 16 — "As a result, people with AIDS now live twice as long as they did a decade ago." Survival time in patients with AIDS is believed to have increased considerably during the past few years. There needs to be some context given to this statement, since it is 15 years since the beginning of the epidemic. Treatment (depending on access to care and when in the course of the disease an individual presents for care) and the course of the disease still varies. "Long term AIDS survivor" is a cruelly relative term. Most people infected with HIV take about 7 years to develop symptoms and 8 or more years to fit a diagnosis of the disease. But even with the best available treatment for AIDS, half the patients die within 2 years of being diagnosed and few live beyond 3.

According to the research literature, women and minorities may have a greater risk of a relatively early death but suggest that important factors may involve poorer access to or use of health care resources. The latest survival information can be updated by NIH and CDC.

Page 12, paragraph 1, lines 1-6 — "The scope and nature of the HIV/AIDS epidemic has brought state, local, and Federal involvement into many AIDS-related activities. The Federal government, through its public health responsibilitities in such areas as research, prevention, health care and housing has seen a dramatic increase in Federal activities since the beginning of the epidemic." The meaning of these two sentences are not clear. In the context of the overall HIV/AIDS epidemic, the Federal government, through HHS, devoted increased resources to address HIV and

AIDS through prevention, research, and services. HUD funding for the Housing Opportunities for Persons with AIDS (HOPWA) was not provided until FY 1992. HHS and HUD have collaborated on housing. Also, the Congress legislated certain funding and programs throughout the epidemic, some with certain restrictions included (e.g., needle exchange, content of education material). The NHSA is based on the knowledge and experience gained in facing the challenges of the HIV epidemic during the 1980s. Clarification is needed.

Page 12, paragraph 2, line 13 "In this case, programs that are specifically targeted towards countries or regions, are included in the international section." Insert "geographic" in front of regions and insert "of the world" after "regions" if this is the intent.

Page 12, paragraph 3, line 5 "There are number of agencies for whom AIDS-specific activities are central to their mission (e.g., the National Institutes of Health (NIH), the Centers for Disease Control and Prevention (CDC), and the Health Resources and Services Administration (HRSA))..." The agencies mentioned are all Public Health Service agencies, that are part of the Department of Health and Human Services. Each of these agencies has health-related missions that encompasses its HIV-related missions.

Page 13, paragraph 1, line 2 ...while other agencies maintain programs and activities that support a broad range of activities, of which HIV-related activities are one among many (e.g., the U.S. Agency for International Development (USAID) and the Department of Justice (DOJ))." The agency and Department mentioned are outside the Department of Health and Human Services, Public Health Service, which was given the lead early on in the AIDS epidemic, because of its health-related mission. As noted in comments (above), the NSHA should clarify the extent of the role of HHS (especially the PHS agencies and HCFA) and then note the relative role of other Departments and independent agencies.

Page 13, paragraph 2 The description of how the report is organized may be confusing. Since HIV/AIDS is a cross-cutting issue across seven of the eight Public Health Service Agencies

that comprise the PHS and HCFA in the Department of Health and Human Services, and further involves a number of cabinet level Departments: Veterans Affairs, Defense, State, for example, and other independent, free-standing agencies, it is recommended that the Office of the National AIDS Policy Director ensures the entire report (including ALL appendices) are provided for comment and review before publication.

Page 14, paragraph 3, line 1 "Prevention activities are currently supported by several Federal agencies. Most Federal prevention efforts are funded by the Public Health Service, although other departments such as the Department of Defense (DoD), and the Department of Veterans Affairs (VA) also support prevention activities." Insert the "HHS" after Public Health Service and see earlier comments to clarify agencies within the same Department early on in the NSHA.

Page 15, paragraph 2, line 1 "The efforts of Federal agencies have been instrumental in expanding our knowledge base about HIV prevention. However, significant gaps remain." After the word "agencies" insert "and Federally funded research, as well as research conducted at universities and private organizations."

Page 16, paragraph 2, line 1 "A crucial part of effective prevention strategies includes supporting adequate surveillance of HIV infection and related diseases in order to estimate the burden of HIV illness, gauge future directions of the epidemic, and assess the effectiveness of prevention activities." Potentially, this sentence on surveillance could be interpreted as used to provide economic estimates of "the burden of HIV disease." In general, efforts have been made NOT to further stigmitize HIV and AIDS by emphasizing costs. We have recognized, given the wide variability in both the course of HIV and AIDS and the new treatments (including drugs), that often private third-party payors do not reimburse for the cost of care for patients with HIV/AIDS and instead shift costs to the public sector which includes Federal programs.

Page 20, paragraph 1, line 1 "As President Clinton has noted, the epidemics of substance abuse and HIV in this country are overlapping and highly interrelated so we must work to integrate HIV prevention into current substance abuse programs

and integrate substance abuse prevention into HIV prevention." It may be appropriate to insert the words "continue to" after "must" since, for example, the Association of State and Territorial Health Officials (ASTHO) and the National Association of State Alcohol and Drug Abuse Directors (NASADAD), along with SAMHSA, CDC, HRSA, and NAPO sponsored the "National Conference on HIV and Substance Abuse" in November 1990 and the National Commission on AIDS issued a report entitled "The Twin Epidemics of Substance Abuse and HIV" in July 1991.

Page 21, paragraph 1, line 1 "...reflects the importance of integrating these inter-dependent aspects of the epidemic and illustrates our determination to integrate and coordinate HIV, STD and TB programs." It is not clear how the reorganization reflects "our determination."

Page 22, paragraph 1 In the discussion of incorporation of sexual history and prevention counseling, mention should be made of the need for training to improve primary care providers' skill, comfort level and sensitivity in this area.

Page 23, section on Research The overall role of the Department of Defense in research needs to be expanded in the text, unless it is clear from the appendices.

Page 23, paragraph 2, line 11 "The Agency for Health Care Policy and Research (AHCPR) funds research to help determine which medical approaches are the most cost effective." After the word "funds" insert "health services."

Page 23, paragraph 3, line 1 "The Nation has already reaped the benefits of supporting research in general, and HIV-related research specifically." Insert the words "some of" before "the benefits". Also, this sentence could be edited to include not only the national impact, but the international impact.

Page 24, paragraph 3, line 1 "Due in great part to this Federally-sponsored research, persons with AIDS now live twice as long as they did a decade ago." Please see earlier note on survival.

Page 25, paragraph 2, line 5 "--mankind has never before encountered a virus such as this." According to NIH, changes in microbes and our environment will continue to present new health challenges worldwide. This sentence is not clear.

Page 26, paragraph 2, line 14 "...one of the areas identified by ADDTF and the Department of Health and Human Services members for further discussion was vaccine development." See previous comments regarding the consistency of the use of the Department of Health and Human Services. In this context, it is recommended that NIH and FDA, and other agencies that participated in the ADDTF be specifically cited.

Page 28, paragraph 2, line 3 "...numbers and at record speed,..." The term "record speed" could be better defined.

Page 28, paragraph 3, line 1 "With the advent of accelerated approval by the FDA it is incumbent on the government to ensure that the post-marketing efficacy studies, currently mandated through regulation are carried out." This needs to be rewritten to clarify that FDA/PHS/HHS is charged with this responsibility.

Page 28, paragraph 3, line 12 "As a result, patients may be receiving less effective treatment or combinations of treatments, and Federal programs such as Medicaid and Medicare and Private insurers may be paying for these less effective treatments. Americans are spending millions of dollars per year on such therapies about which little is known." These sentences are not clear and could potentially be interpreted as a reason to <u>not</u> pay for clinically indicated therapies, and involve several complex issues, including, allowing clinical trials to use surrogate markers of disease progression and of drug efficacy. Also, the Ryan White CARE Act reimburses for prescription drugs.

Page 33, paragraph 1, line 1 "...Treatment and primary care must come before ancillary services." The document may need to define "ancillary." This statement could have far reaching policy implications, especially for the AETC Program. The Senate Appropriations Committee language appears to indicate the Senate's desire to move the decision for

funding provider training to the local planning bodies. "Increasing access to, and support of, treatment and primary care...." would be a better choice of words.

Page 33, paragraph 4, line 11 "...schools, and professional organization in addition to local and Federal governments." Insert "State" after the word "local."

Page 35, paragraph 1 Four of the five agencies provided as examples in this paragraph reside in the Department of Health and Human Services, Public Health Service (SAMSHA, HRSA, CDC and NIH). While uniform applications are administratively possible, the statutes and regulations may have to be amended to accomplish this.

Page 38, paragraph 1, line 5 "Based on the Vice President's initiative to bring the lessons back home through the "Lesson without Borders Project" to inner city and rural areas with problems similar to those experienced overseas,..." A footnote to this project may be necessary to those who are not familiar with its content (source and date).

Page 40, paragraph 1, line 5 "NIH's state-of-the-art conferences have also contributed to improving the translation of research results into clinical practice." Examples of what these "state-of-the-art" conferences are and when they were held would be useful (it could be as a footnote).

Page 41, paragraph 3, line 16 "The Health Care Financing Administration (HCFA) also enforces regulations regarding the treatment of HIV-infected persons." This appears to be the first time this agency, an agency in the Department of Health and Human Services that adminsters the Medicare and Medicaid programs is specifically mentioned. Also, the NSHA needs to clarify how the HCFA regulates (perhaps an example could be included).

Page 42, paragraph 2, line 8 "The Administration will also continue to oppose Congressional attempts to force discharge of infected military personnel who are still able to serve their country." Since the Defense Department's bill has already been signed by the President, this sentence needs to be modified and include the Departments that will be taking the lead in this effort.

(Care and Services)

Page 4, paragraph 1, line 3	Add to "evaluate program effectiveness." "...Agree to common evaluation criteria of CARE Act grants that address program delivery and program outcomes. Also establish evaluation measures that are unique to each Title."
Page 4, paragraph 5	Add to "constituency involvement:" "Nationally, focus groups, workshops, and discussion groups of PWAs, providers of HIV care, State and local officials, and researchers review proposed policies, program directives, and planning and evaluation activities to ensure constituency input."
Page 4, paragraph 8	Unmet Need: Add "...There is need for increased access to 1% evaluation funds for service-related evaluations."
page 6	Regarding question: Are there separate funds for the SPNS evaluation? Answer: No, all of the funds come from 10% tap from Title II.
	<u>Add</u>:
	Objective: Ensure funding and dissemination of innovative models of care that evaluate all of the major care and service goals listed in this plan: effectively educated providers, increased access to and quality of care, reduction of perinatal transmission of HIV.
	Action Steps: Review currently funded SPNS projects to identify gaps in project coverage for future Requests for Applications (RFAs).
	Populations served: CARE Act grantees.
	Constituency Involvement: Health care providers, evaluation researchers, communication experts, and patient advocates.
page 9	I would suggest adding this to unmet need under the reduction of perinatal transmission: " In particular, it is

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

Goal of the National Strategy

The purpose of the national strategy is to establish national goals and identify opportunities for progress for 1996 in order to chart our course in combatting the epidemic of HIV and AIDS. To ensure efficient use of Federal, State, local, and private resources, it is imperative to plan and coordinate government-wide efforts.

This is the first time a government-wide national strategy for HIV and AIDS for the United States has been developed. This strategy links programs to national objectives in each federal agency that supports AIDS-related activities. It lays forth the national goals and emphasis areas for HIV/AIDS, documents current Federal activities, and links goals to budget objectives based on current scientific opportunities, public health needs and priorities, and fiscal constraints. It is intended to be a living document that will be updated regularly. By establishing a government-wide baseline, this plan will help guide Federal agencies in refining their goals and objectives in response to the changing face of the epidemic of HIV and AIDS.

The national strategy for HIV and AIDS presented here is broader in scope than prior planning efforts. To date, planning has been primarily focused in the Public Health Service as evidenced by a series of documents such as the ~~Public Health Service~~ Plan for the Prevention and Control of Acquired Immune Deficiency Syndrome[4], the "Coolfont"[5] and "Charlottesville"[6] reports, and the PHS Strategic Plan to Combat HIV and AIDS in the United States[7]. Recommendations have also been issued from a number of groups, including the National Commission on AIDS[8] in addition to significant planning efforts on the part of individual agencies. However, there has not been a national plan that provides for a government-wide coordinated effort encompassing not just Public Health Service activities, but also incorporates issues such as housing, health care, and civil rights. This strategy addresses this important need. Moreover, realizing the goals of the strategy will require continued consultation and planning with Federal departments and agencies, and with the infected and affected communities.

Common Goals and Opportunities for Progress

This national strategy for HIV and AIDS has been developed from the bottom up. Through the Interdepartmental Task Force on HIV and AIDS (IDTF), a group that consists of representatives from executive branch departments and agencies that conduct AIDS-

transmission, and perinatal transmission. Moreover, the youth of our country are becoming infected at an alarming rate -- 50 percent of new infections in the United States are in persons under 25 years of age. HIV is the leading cause of death in Americans aged 25 to 44 and it is likely that many of these people were infected while they were adolescents. Racial and ethnic minorities are also disproportionately represented among new HIV infections. As of October 1995, African-Americans accounted for 38 percent of newly reported AIDS cases and Hispanics represented 18 percent of new cases. These trends in the epidemic must be taken into consideration when prioritizing prevention research and service programs.

A crucial part of effective prevention strategies includes supporting adequate surveillance of HIV infection and related diseases in order to estimate the burden of HIV illness, gauge future directions of the epidemic, and assess the effectiveness of prevention interventions. As previously noted, the CDC is the Federal agency with primary responsibility for monitoring the epidemic. The CDC AIDS case and case death reporting system provides useful data for assessing AIDS prevalence and mortality by gender, race/ethnicity, age, and mode of exposure. This surveillance system also provides essential data on HIV-related opportunistic infections.

There are, however, opportunities for refinement. Effective prevention intervention programs begin with sound information on who is at risk. Current CDC surveillance systems do not currently capture sufficient "front-end" information on the incidence and prevalence of HIV (not AIDS) in the population, and trends in modes of transmission and new infections. (These data must be collected with the appropriate confidentiality protections.) Collection of these data are needed as part of an enhanced effort to link surveillance and epidemiological data to priority setting, in addition to the design and evaluation of prevention programs. The CDC has recognized the value of this approach and has incorporated data collection design into its community planning process. These shifts in data needs also require that the CDC reevaluate and reconfigure its data collection efforts; such a change may require reconfiguring of currently collected data to address these needs. As part of the agency's implementation of the recommendations set forth in the external review of CDC's HIV prevention strategies', the CDC has initiated efforts to evaluate current data collection efforts and implement necessary changes, and this work should continue.

Gaps in Scientific Knowledge

In HIV and AIDS, this intervention research can focus on both individuals and communities, which often hold norms that influence personal behavior. Since the beginning of the epidemic we have made advances in our understanding of factors that are relevant to the design of intervention programs intended to reduce rates of HIV infection. This theoretically based intervention research has identified several significant predictors of changes in sexual and drug-using behaviors among gay men, adolescents, and heterosexual adults.[12] Studies have shown that community based HIV risk reduction programs that are gender relevant and culturally sensitive can be effective.[13] A recent study has also provided a reason for optimism that the spread of HIV can be contained among injecting drug user populations when there is early community outreach and access to sterile injection equipment.[14]

However, despite these successes, there is more that we need to know if we are to develop effective prevention programs for a diversity of Americans. We must incorporate findings from basic behavioral research into effective prevention interventions. One high priority area is research regarding strategies that facilitate sustained adoption and maintenance of HIV preventive behaviors. Another area for investment is research on cultural barriers and strategies to reach populations resistant to behavior interventions. A third area is research on the effectiveness of treatment for drug abuse, mental illness, and alcoholism for reducing HIV risk behavior. Agencies supporting intervention and behavioral research must include scientists from a broad range of disciplines in their planning activities and improve their data-sharing and collaborative efforts with agencies responsible for implementing prevention programs. Enhancing the dialogue between researchers in these two related disciplines will invariable improve the development of effective prevention interventions.

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

We know from efforts in other countries that HIV related social

Center for HIV/STD/TB Prevention at CDC reflects the importance of integrating these inter-dependent aspects of the epidemic and illustrates our determination to integrate and coordinate HIV, STD, and TB programs.

Harm Reduction.[3] In addition to efforts directed towards enrolling drug users in treatment programs for their addiction(s), harm reduction should be considered by communities when treatment fails or is unavailable. Although harm reduction programs for drug users have not been well accepted in our country, experts feel that it is in this area that we may be able to make a significant impact in stemming the tide of the epidemic.

There is scientific evidence that controversial harm reduction approaches, such as needle exchange programs, can be effective. Among the conclusions presented in a recent report by the Institute of Medicine was that there is no credible evidence that drug use is increased among participants as a result of needle exchange programs that provide legal access to sterile equipment. The IOM also concluded that the lower the fraction of needles in circulation that are contaminated, the lower the risk of new infections. They went on to recommend that needle exchange programs be regarded as an effective component of a comprehensive strategy to prevent infectious disease.[4] There is also evidence that needle exchange programs provide an opportunity to get people into treatment, thereby further reducing their risk and the risk for their sexual partners.

While the data strongly support the effectiveness of needle exchange programs in preventing the spread of infection, ~~we continue to believe that~~ decisions regarding these approaches should be a community decision based on local epidemiology. ~~We also believe that certain existing statutes restrict potential prevention efforts~~. The Federal government will work with state and local officials to provide the information they need to take advantage of this intervention.

[3] Harm reduction efforts support people by reducing their risk of HIV transmission by teaching behaviors that do not transmit HIV. In the case of HIV and substance abuse this can include: needle exchange programs, decriminalization of needle and syringe possession, legalizing syringe purchases without prescription, increasing the availability of clean syringes, providing information on cleaning injection equipment ("cleaning works"), and reducing needle sharing behaviors.

many! Soul 77

delete the personal "we believe"

If "we" believe this then why not have the Surgeon G. Jen. approve? I would delete or the Secretary puts HHS's the WH in a box!

significant role in our search for a cure and a vaccine for HIV. If the government is to effectively support a diversity of promising approaches, these research efforts must also be well-planned, coordinated, and maintain accountability. To achieve this the Director of the Office of National AIDS Policy will coordinate an inter-departmental working group, chaired by the Director of the Office of AIDS Research, whose charge is to develop a coordinated plan and budget specifically for HIV and AIDS research across all departments.

Vaccine Development. Reaching the goal of developing a vaccine will require the joint commitment of government and the private sector. Several challenges currently face the U.S. and the world in continuing the vaccine development effort. The first is to meet the daunting scientific challenge and the second is to create an environment where the private sector can effectively join in partnership with the Federal government. The National AIDS Drug Development Task Force (ADDTF), which included representatives from government, the private sector, and the activist community, identified a range of approaches to accelerating the development of therapeutics for HIV infection. And while the ADDTF focused primarily on the development of HIV-related therapeutics and not vaccines, one of the areas identified by ADDTF and the Department of Health and Human Services members for further discussion was vaccine development. Further dialogue involving key players in this areas was deemed as essential in determining and overcoming critical problems and identifying opportunities for development.

Therefore, in order to identify areas for fruitful collaboration and to accelerate the pace of development for vaccines, President Clinton has asked the Vice President to convene a meeting of government scientists and leaders of the pharmaceutical and biotechnology industries to identify barriers to the development of these agents.

How has this happened already? Why not ask DES, his Sec. of HHS to convene?

At present researchers hold two major views regarding the most promising approaches to vaccine development. Some scientists believe that we need to return to basic science to gather more information to guide us, while others believe that only efficacy trials will provide the answers that really matter and in the face of a global emergency we must empirically test candidate vaccines in people immediately. Both groups have valid arguments.

The issues driving this debate are both scientific and social, with different parts of the world experiencing the epidemic in different ways. Some regions of the world have already experienced the devastating consequences of the epidemic while,

CARE & SERVICES

One of the national goals is to ensure appropriate care for all persons living with HIV and AIDS. For many of these persons, maintaining adequate health insurance coverage can be extremely challenging. There are many who exhaust their personal resources and private sector options over the course of their illness and are left to rely on the nation's medical care safety net. Achieving the goal of ensuring appropriate care of all Americans, including those living with HIV, will require a dedicated alliance among the Federal government, states, the private sector, local communities, community-based organizations, clinics, families, and individuals.

Background

Persons living with HIV finance needed health care services through a variety of mechanisms. Currently, nearly 50 percent of adult Americans living with AIDS receive their medical coverage through the Medicaid program and another 5 percent receive Medicare benefits. An estimated 15 percent of people living with AIDS have private health insurance and the remaining 30 percent are uninsured and must rely on personal payment or charity care. For the remainder, their lives often depend on the Federal health care safety net. (See Appendix C.)

For those that qualify, care and services are provided through a number of Federal agencies, many in cooperation with local organizations and the AIDS community who have admirably served those living with HIV. Taken together, these efforts form a valuable if incomplete safety net for some of the most vulnerable people in our Nation. By far the largest sources of care for persons living with HIV are Medicaid and Medicare. For Americans living with HIV, Medicaid is the single largest source of health care financing, providing coverage for nearly 50 percent of adults and more than 90 percent of children living with AIDS.

A second major source of care is provided through Ryan White Comprehensive AIDS Resources Emergency (CARE) Act of 1990, administered by the Health Resources and Services Administration (HRSA); it was established to fill certain gaps in coverage for people living with HIV/AIDS. Titles I and II of the CARE Act provide funds for outpatient care, support services, and case management that are given to cities and states primarily on a formula basis so the areas most affected by the epidemic receive a proportional share of available dollars. Title II also provides drug reimbursement funding for persons living with AIDS. Title III of the Act provides early intervention services such as

counseling and testing, medical care, and educational services for medically underserved persons with the goal reducing HIV-related illness. Title IV seeks to increase the availability of care and services for women, infants, children, and youth in a community-based family-centered system of care. HRSA also provides primary care to persons living with HIV through its Community Health Centers and Maternal and Child Health Programs. Housing assistance is provided by the Department of Housing and Urban Development (HUD) through their Housing Opportunities for Persons with AIDS (HOPWA) and other programs.

Opportunities for Progress

The challenge before us today, especially in light of the restricted fiscal environment, is to ensure that persons living with HIV receive the care they need so they may have the opportunity to live productive lives. To achieve this, AIDS care and service programs must build upon past successes, continue to improve prioritization efforts, improve accountability, and increase the cost-effectiveness of services they provide.

The Health Care Safety Net. We must continue to adequately fund the program that is the cornerstone of care -- Medicaid. Medicaid is the lifeline of support to millions of Americans. It provides access to doctors, hospitals, treatments, and home care -- the services that allow people to live longer more productive lives. Present Congressional plans to cut the Medicaid program overall by $169 billion and turn it into a block grant in effect reverses this Nation's 30 year National commitment to the poor and those in need. Cutting Medicaid to this level would cut the lifeline for millions of Americans, including those living with HIV and AIDS. Maintaining this program in a viable format must be a National priority.

With the potential cuts in Medicaid and welfare, the importance of the public health safety net increases for all vulnerable populations -- disproportionately so for people with AIDS. This will require several responses. First, no one Federal program will be able to absorb the unmet need that may be created by proposed changes to the Medicaid, Medicare and welfare programs. All Federal programs, along with state and local organizations, must share the responsibility for serving and caring for people with AIDS. This must include the full integration of HIV-related care into programs that serve the needy, such as community health centers. Second, it is important that programs such as those funded under the CARE Act receive sufficient funding so as to maintain the safety net. In addition, AIDS programs must do a better job of prioritizing what services they can provide -- and

THIS DEPARTS FROM HEALTH STRATEGY TO POLITICAL DOCUMENT

A SIMPLE DISCUSSION OF THE IMPORTANCE OF MEDICAID IS MORE CRITIQUE OF POTENTIAL CONGRESSIONAL ACTION WILL MAKE THIS DOCUMENT MORE ENDURINGLY RELEVANT

MOREOVER, THESE STATEMENTS COULD TAKE THE PRES. DOWN A POLICY PATH THAT HE MAY CHOOSE, FOR WHATEVER REASON, NOT TO GO DOWN.

CDC comments on *National Strategy for HIV and AIDS*

Please note: substitute words, phrases and paragraphs are located, with page number, paragraph, line number within the paragraph. In places where the wording is changed or substituted, the recommended replacement words or sentences are shown in *italics*.

(Page 5, first paragraph)
The pandemic of *human* immunodeficiency *virus* (HIV) and *acquired immunodeficiency syndrome*... Unlike ~~most~~ other infectious diseases..... This national and international pandemic of HIV diseases, now well into its second decade, is *still* progressing ~~virtually unabated~~ *in many areas*.

(Page 5, second paragraph)
Reword as follows: As of October 1995, the Centers for Disease Control and Prevention (CDC) *has* reported 501,310 cases of AIDS *among persons* in the U.S.; 311,381 *of these persons have been reported to have* died as a result of complications related to HIV. Since 1987, AIDS has gone from being the 15th ranked cause of death *among all Americans* to the 8th; *but*, it is the leading cause of death among Americans aged 25 to 44. (See Figure 1.) In 1994 alone, approximately 81,000 new cases of AIDS *and more than 45,000 deaths* were reported to the CDC.....

(Page 5, third paragraph)
~~As we have witnessed a relentless increase in infections~~, *the epidemic in the United States has evolved*, the demographics.... ; this group now represents less than half ~~(43%)~~ of all new cases. Among the populations being more heavily affected now are young *gay* men, ~~between 20 and 24 (%)~~ women ~~(18%)~~, and heterosexual injecting drug users ~~(24%)~~. [Take out percents-they are not comparable, e.g. Women can be IDUs and between 20-24. There can be overlap in most of these groups.]

(Page 5, third paragraph, 11th line)
In 1995*4 alone*, more than 14,*000* women were *reported* with AIDS and women now comprise *14* percent of 21 percent .... It is estimated that if this trend continues, 80,000 American children will have been orphaned *as a result of* AIDS by the ... (Drop the sentence "As of October 1995...." This is not true) In 1994 alone, more than 1,000 new pediatric AIDS cases were reported.

(Page 6, first paragraph, 1st line)
Communities of color *have been* more severely and disproportionately affected *by the epidemic*.

(Page 6, first paragraph, 7th line)
In 1982, ~~persons of color~~ *blacks and Hispanics* represented ~~only~~ *31* percent of *all* AIDS cases, as of October 1995 *these groups* now compromised *51* percent of *cumulative* AIDS cases. [Drop last sentence of this paragraph]

(Page 6, second paragraph)
[This paragraph is redundant; all data has previously been given]

(Page 6, third paragraph, 2nd line)
The HIV/AIDS pandemic is spreading to *nonurban* areas....regions of the *South and Midwest*. In fact, between 1993 and 1995 the largest numbers....from the South. [drop the remainder of the sentence.

(Page 6, last paragraph, 2nd line)
The World Health Organizations (WHO) estimates that since *the beginning of the epidemic, 4.5* million cases of

AIDS have occurred worldwide. (Keep next sentence as is) ..... WHO also projects that by the year 2000 *between 30-40* million people will *have been* infected with HIV.

(Page 7, first paragraph, 6th line)
And unlike other persons .....living with HIV ~~to~~ have been the target...

(Page 7, second paragraph, 3rd line)
[Drop third sentence "It is the leading cause.....25 to 44" This is redundant with earlier text]

(Page 7, second paragraph, 8th line)
~~In terms of years of potential life lost,~~ In 1994, ~~AIDS ranked~~ *HIV infection was the* fourth ~~among all leading causes of death~~ *leading cause of years of potential life lost before age 65.*

(Page 14, first paragraph, 3rd line)
The Nation's prevention goal is to ~~provide solid support for~~..... [Suggest that providing "solid support" is not a goal.] Restate: The Nation's prevention goal is to *develop* effective prevention strategies *that will* reduce...

(Page 15, third paragraph, 3rd line)
Recent epidemiologic data show that the *HIV epidemic continues to* ~~strengthen~~ *spread in the United States among* people who engage in injection drug use and their sexual partners, *young and minority* men having sex with men, ...

(Page 16, first paragraph, 1st line)
A crucial part of the effective prevention .....in order to estimate the ~~burden~~ *impact* of HIV illness...

(Page 16, first paragraph, add to the end of paragraph)
Seroprevalence surveys provide information on the level of HIV infections on selected "sentinel" populations.

(Page 16, second paragraph, 3rd line
Current CDC surveillance systems ....on the incidence ~~and prevalence~~ of HIV (not AIDS)....

(Page 18, third paragraph, 7th line)
Given the highly....the CDC must give ~~consider~~ *consideration to* providing....
(Page 20, second paragraph, 4th line)
It is estimated that x percent of the population...is affected by alcohol and other drugs in addition to injection drug use. [CDC is not aware of any such estimated data - perhaps SAMHSA or NIDA can provide this information.]

(Page 25, 3rd paragraph, 15th line)
Misspelling "sound scientific judgement and ..." The preferred and standard spelling is "judgment". We suggest that a Search and Replace function be used for the entire document.

(Pages 47 through 50, - 4 CDC map illustrations)
Suggest that they be placed in a progressive date sequence (i.e., 1983, 1985, 1989 and 1994).

CDC Prevention Goals and Objectives (No page numbers were given to reference)

We strongly suggest that the information in this section be replaced with the latest version of the *Healthy People 2000 Objectives* (as displayed in *Healthy People 200 Midcourse Review and 1995 Revisions*). The

information you have displayed was developed during CDC's 1991-1992 HIV Strategic planning process and although still relevant, will be updated later this year in a new strategic planning activity.

However, if this section is kept, we suggest the following changes:

Under Goal: More accurately monitor the HIV epidemic....

> **Objective:** Work with international partners to study TB, implement vaccine trials, enhance clinical management, assess prevention efficacy, and improve program management of HIV/AIDS. [Relevance to goals?] Comment: This objective *is* relevant.

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

Under Goal: Increase the public understanding of, involvement in.....

Objectives: Provide leadership in HIV and STD prevention by (1) establishing a national agenda, through the media, *that keeps the HIV/AIDS interests "active" on the national agenda as a topic that is routinely covered by local and national news media.*

Descriptions: [include *Prevention Marketing Initiative* at the end of the first paragraph, following CDC National AIDS Hotline]
In addition....National AIDS Clearinghouse, the CDC National AIDS Hotline, *and the Prevention Marketing Initiative.*

Descriptions: [following the dollar estimates given for FY 95 and FY 96] include the statement: *These are aggregate estimates provided by States.*

Approval: _____ 2/26/96
Div., NCHSTP Date

2/27/96

NOTE TO EXEC SEC:

Subject: Document #148506 - National Strategy for HIV and AIDS

The OAR has not had sufficient time to draft our very lengthy review of this document. We have serious concerns about scientific inaccuracies, research priorities, and the structure of the document, which will require significant rewriting.

For these reasons, we must nonconcur with the document at this time.

Jack Whitescarver

Jack Whitescarver, Ph.D.
Deputy Director
Office of AIDS Research

Harold Varmus

DEPARTMENT OF HEALTH & HUMAN SERVICES Public Health Service

Substance Abuse and Mental
Health Services Administration
Rockville MD 20857

MAR 8 1996

TO: Executive Secretariat, OS

FROM: Administrator, SAMHSA

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

Thank you for the opportunity to review and comment on the Draft of the National Strategy for HIV and AIDS. This is a well documented report on the status of this national epidemic. As well, it provides a holistic view of our present Public Health Service activities and strategies that will be necessary in the future. As requested, we have attached our comments regarding our individual plan and comments to the full draft.

Nelba Chavez, Ph. D.

Attachments

NATIONAL STRATEGY FOR HIV AND AIDS

SAMHSA REVISED HIV/AIDS-RELATED ACTIVITY DESCRIPTIONS

The following italicized changes should be included in the final description of SAMHSA's current HIV/AIDS related activities:

CARE AND SERVICES

Descriptions: HIV/AIDS Mental Health Services Demonstration Program
FY96: $1,500,000 *To Be Determined*
($1,400,000 NIH and $1,500,000 HRSA)

Descriptions: HIV/AIDS Community Outreach Program
FY96: $7,500,000 *To Be Determined*

Goal: *Improve HIV/AIDS training of clinicians*
Descriptions: AIDS Health Care Worker Training
FY96: $2,930,000 *To Be Determined*

Descriptions: The Linkage Initiative
FY96: *To Be Determined*
Constituency Involvement: *Service providers, consumers*

PREVENTION

Descriptions: High Risk Youth Program
FY96: $3,000,000 *To Be Determined*

Descriptions: Demonstration sites and community training in the use of HIV/AIDS curriculum
FY96: $5,000,000 *To Be Determined*

Objective 3: *Improve training of Faculty Development Program (FDP) grantees*
Descriptions: *Supplementation of Faculty Development Program (FDP) grantees*
FY96: $650,000 *To Be Determined*
Populations Served: *General public*

PREVENTION

Agency: Health Care Financing Administration

Goal: Reduce perinatal transmission among Medicaid-eligible women.

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

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

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

FY 95: ~~Federal resources to be determined.~~ $50,000 (Edelman)
FY 96: Federal resources to be determined.

Populations Served: HIV positive women eligible for Medicaid coverage.

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

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

CARE AND SERVICES

Agency: Health Care Financing Administration

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

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

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

Description: Medicaid primary health care services.

FY 95: 1,540,000,000 (Federal share)
FY 96: 1,800,000,000 (Federal share)

Populations Served: HIV positive Medicaid-eligible persons.

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

Unmet Need: NA

CARE AND SERVICES

Agency: Health Care Financing Administration

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

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

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

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

Develop directives in implementation of developed guidelines.

FY 95: ~~Federal resources to be determined.~~ $25,000 (conference materials)
FY 96: Federal resources to be determined.

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

Constituency Involvement: Significant constituent consultation throughout course of project development. ~~Other groups?~~ (provider groups)

Unmet Need: Implementation of directives dependent on nature and resources of each project partner. ~~A little more detail needed.~~

Revised 2/20/96.

Administration | CARE AND SERVICES

Agency: ~~Agency~~ for Children and Families, DHHS.

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

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

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

Descriptions: Runaway and Homeless Youth Program.

FY 95: NA -- HIV services integrated into overall budget.
FY 96: NA -- HIV services integrated into overall budget.

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

Constituency Involvement: A network of more than 500 grantees, both public and private ~~Advocacy Groups? Service Organizations?~~

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

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

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

Descriptions: Child Welfare Services Program.

FY 95: NA -- HIV services integrated into overall budget.
FY 96: NA -- HIV services integrated into overall budget.

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

Constituency Involvement: ~~Advocacy Groups? Service Organizations?~~

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

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

Action Steps: Provide foster care, health services, counseling and other social services, ~~and recruitment and interdisciplinary training~~.

Descriptions: Abandoned Infants Assistance Program.

→ National professional, advocacy, and service organizations such as The Child Welfare League of America, American Public Welfare Association, National Association of Social Workers, and 50 State/Territorial agents.

FY 95: NA -- HIV services integrated into overall budget.
FY 96: NA -- HIV services integrated into overall budget.

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

Constituency Involvement: Public and private providers of these services, grantees, and national resource centers

Resources to serve geographic areas of unmet need.

Unmet Need: [redacted] ↓ The Head Start program | child development

Objective 4: Provides comprehensive services to children, including those with HIV/AIDS, their parents, and families.

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

Descriptions: Head Start Program.

FY 95: NA -- HIV services integrated into overall budget.
FY 96: NA -- HIV services integrated into overall budget.

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

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

Increased resources will make services available to more children.

Unmet Need: [redacted] ↓

Objective 5: ~~Provide assistance and services to increase and~~ Support the independence, productivity, and integration into the community of persons with developmental disabilities.

Action Steps: ~~Support the~~ twenty-seven of the current 51 grantees operating pediatric HIV/AIDS clinics in or associated with the university.

Descriptions: University Affiliated Program

FY 95: NA -- HIV services integrated into overall budget.
FY 96: NA -- HIV services integrated into overall budget.

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

Constituency Involvement: ~~Advocacy groups, service organizations~~ National network of grantees; national advocacy organizations related to HIV/AIDS and developmental disabilities.

Unmet Need: [redacted] ↓

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

Scope of the HIV/AIDS Pandemic

The pandemic of Human Immunodeficiency Virus (HIV) and Acquired Immunodeficiency Syndrome (AIDS) presents unique social, economic, and public health challenges to people and governments here in the United States and worldwide. Unlike other infectious diseases that have arisen over the course of history, HIV is infectious for life and almost always fatal. This national and international pandemic of HIV disease, now well into its second decade, is progressing virtually unabated. It also remains a deadly infection for which there are limited treatments, no vaccine, and no cure.

An Expanding Public Health Threat

As of October 1995, the Centers for Disease Control and Prevention (CDC) reports that cumulative a total of 501,310 cases of AIDS have been diagnosed in the U.S. and an estimated 311,381 Americans have died as a result of complications related to HIV. Since 1987, AIDS has gone from being the 15th ranked cause of death to the 8th and it is now the leading cause of death among all Americans aged 25 to 44. (See Figure 1.) In 1994 alone, approximately 81,000 new cases of AIDS were reported to the CDC and over 44,000 Americans died of AIDS-related causes in 1994. The CDC estimates that between 40,000 and 60,000 Americans are becoming newly infected with HIV each year, and that between 800,000 and one million Americans are currently living with HIV.

As we have witnessed a relentless increase in infections, the demographics of the epidemic have been shifting. The early years of the epidemic were dominated by cases involving gay or bisexual men living in major urban centers, such as New York, San Francisco, and Los Angeles; this group now represents less than half (43%) of all new cases. Among the populations being more heavily affected now are young men between 20 and 24 (%), and women (18%), and heterosexual injecting drug users (24%). And although gay men no longer represent the majority of new cases, this groups represents the majority of persons living with HIV and AIDS. In 1995 alone, more than 14,xxx women were diagnosed with AIDS and women now comprise 21 percent of cumulatively reported AIDS cases. It is estimated that if this trend continues, 80,000 American children will have been orphaned by AIDS by the end of this decade.[4] As of October 1995, pediatric

of AIDS cases, as of October 1995 this group now comprises x percent of new AIDS cases. Moreover, in certain regions of the country gay men of color account for approximately 39 percent of new AIDS cases. Young gay men of color aged 10 to 24 are especially hard hit, representing 53 percent of new AIDS cases nationwide.

The proportion of cases due to the common modes of transmission are also changing. The CDC estimates that in the United States approximately 50 percent of all new cases are now related directly or indirectly to substance abuse, particularly the use of injectable drugs. As a result, the incidence and prevalence of HIV infection in injecting drug users (IDUs) and their sexual partners and their children is rising.

Moreover, AIDS is no longer just an urban problem. The HIV/AIDS pandemic is spreading to rural areas, including dramatic increases in certain regions of the south. In fact, between 1993 and 1995 the largest numbers of AIDS cases (86,462) were reported from the south, which also accounted for the largest proportionate increase in cases (31%).[3] While most cases are still reported from urban areas, the rate of reported cases in non-metropolitan areas is increasing faster than in urban areas. AIDS cases have now been reported in all 50 states, the District of Columbia, Puerto Rico, and each of the American territories. (See Figure 2.)

Internationally, the toll of the epidemic is even greater. The World Health Organization (WHO) estimates that since 1981, 2.4 million cases of AIDS have occurred worldwide. It has estimated

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[4] It is anticipated that this trend could be reversed with the implementation of the PHS recommendations for the administration of AZT to women during pregnancy and to their infants after birth.

2 - where is footnote 2?
Why are some footnotes here and others at the end of the report?

Letter from the Director of the Office of National AIDS Policy

edits

The national epidemic and international pandemic of HIV and AIDS is a public health crisis of unprecedented proportions; it is the health crisis of this century. The HIV/AIDS epidemic poses a continuing public health crisis that requires solid support for multiple approaches to finding a cure and a vaccine. We must also persevere in our efforts to promote prevention, care, and the ethical treatment of persons with AIDS.

This is the first time a government-wide national plan for the United States has been developed for fighting HIV. It links programs to national objectives. Such a plan was one of the recommendations put forth in 1993 by the National Commission on AIDS. The President, as part of his strong commitment to assuring an efficient coordinated effort, requested that the Office of National AIDS Policy develop a comprehensive plan to guide the federal response to this epidemic.

The Office of National AIDS Policy (ONAP) was created by President Clinton in 1993 to provide greater national focus and direction for the Federal government's response to HIV and AIDS. ONAP is an integral participant in the development of Federal AIDS policies, including annual budget requests and legislative initiatives. As Director of ONAP, I also serve as the head of the U.S. delegation to the United Nations Joint Programme on HIV/AIDS and other international forums.

True government-wide planning requires a commitment from all departments, agencies, and all levels of government to work together toward clearly defined goals. Therefore, this strategy for HIV and AIDS has been developed from the bottom up. Through the Interdepartmental Task Force on HIV and AIDS (IDTF) a request went out for the executive branch agencies to identify their activities, goals, and objectives. With leadership from the President and in partnership with the departments and agencies that are members of the IDTF, we have taken unprecedented steps to prospectively assess and map out future action. As presented here, the national strategy establishes a baseline of current efforts government-wide, links goals to budget objectives, and guides us in refining our goals and objectives in response to the changing face of the epidemic of HIV and AIDS. It is intended to be a living document that will require regular updating as goals are reached and replaced with new challenges.

The purpose of this comprehensive national strategy is to set

- Strengthening HIV prevention activities;
- Supporting diversified research approaches;
- Strengthening approaches to substance abuse treatment and prevention;
- Strengthening the health care and services safety net;
- Improving translation of research results into medical practice; and,
- Improving evaluation and priority setting.

Suggest that these listed be in the same order as the goals — or indicate different priority.

Within each substantive section (i.e., prevention, research, care and services, international activities, translation of research into clinical practice, and civil rights) of this strategy, there is specific discussion about opportunities for progress that are relevant to that substantive area.

Challenge of the HIV Epidemic

Since the discovery of the first AIDS cases in the early 1980s, the epidemic of HIV and AIDS has posed a series of unique challenges. But, the challenges we face today are very different than challenges we have faced so far. It is a growing epidemic in which more persons are infected every year, in every geographic area, every ethnic and racial group, and every age range. We now know how it is transmitted, the etiologic agent, and we have a test to diagnose infected persons and protect the blood supply. And thanks to behavioral researchers and the innovative outreach and prevention strategies developed by community groups, we have prevention models that work. The challenge before us now is to build on these successes and develop prevention interventions that reach even more Americans at risk for infection. Thanks to clinical research, significant progress has been made in drug development and clinical care. As a result, people with AIDS now live twice as long as they did a decade ago. And with the results of the NIH-sponsored research we now have the ability to prevent perinatally acquired HIV infection in some newborns by treating women with AZT during pregnancy.

A significant challenge facing the country now is ensuring access to prevention services and medical care for the growing number of people who are currently disenfranchised from the health care system. We need to improve our efforts in providing people with care early in their infection so they can receive quality health care. We also need to train health care professionals so they know the best way to provide that care. Strengthening our prevention efforts has never been more important. Developing prevention messages that are specially targeted to the group or

CARE & SERVICES

One of the national goals is to ensure appropriate care for all persons living with HIV and AIDS. For many of these persons, maintaining adequate health insurance coverage can be extremely challenging. There are many who exhaust their personal resources and private sector options over the course of their illness and are left to rely on the nation's medical care safety. Achieving the goal of ensuring appropriate care of all Americans, including those living with HIV, will require a dedicated alliance among the Federal government, states, the private sector, local communities, community-based organizations, clinics, families, and individuals.

INSERT #1

Background

Persons living with HIV finance needed health care services through a variety of mechanisms. Currently, nearly 50 percent of adult Americans living with AIDS receive their medical coverage through the Medicaid program and another 5 percent receive Medicare benefits. An estimated 15 percent of people living with AIDS have private health insurance and the remaining 30 percent are uninsured and must rely on personal payment or charity care. For the remainder, their lives often depend on the Federal health care safety net. (See Appendix C.)

For those that qualify, health care and services are provided through a number of Federal agencies, many in cooperation with local organizations and the AIDS community who have admirably served those living with HIV. Taken together, these efforts form a valuable if incomplete safety net for some of the most vulnerable people in our Nation. By far the largest sources of care for persons living with HIV are Medicaid and Medicare. For Americans living with HIV, Medicaid is the single largest source of health care financing, providing coverage for nearly 50 percent of adults and more than 90 percent of children living with AIDS.

A second major source of health care is provided through Ryan White Comprehensive AIDS Resources Emergency (CARE) Act of 1990, administered by the Health Resources and Services Administration (HRSA); it was established to fill certain gaps in coverage for people living with HIV/AIDS. Titles I and II of the CARE Act provide funds for outpatient care, support services, and case management that are given to cities and states primarily on a formula basis so the areas most affected by the epidemic receive a proportional share of available dollars. Title II also provides drug reimbursement funding for persons living with AIDS. Title III of the Act provides early intervention services such as

CARE AND SERVICES - INSERT #1 page 31

In addition to health care and insurance coverage, persons with HIV/AIDS may need a range of social and support services -- for themselves and for relatives, extended family, dependents, and others. These services may include counseling, special education and prevention services for youth, including runaway and homeless youth, group support services, transportation meals-on-wheels, estate planning, and planning for the adoption or long-term care of dependent children who will become orphaned by the death of parents.

The children with HIV/AIDS, although comparatively small in number, often need specialized in-home foster care and developmental services in addition to appropriate health care.

CARE AND SERVICES --- INSERT #2 page 32

Social and support services are provided under the auspices of a range of public and private agencies and organizations operating at the State and local community level.

The Administration for Children and Families funds broad social programs which serve persons with HIV/AIDS as they would all others in the eligible population. Five major programs which serve pregnant women, children, youth, and families are the Head Start program, the Abandoned Infants Assistance program, the Child Welfare program, the Runaway and Homeless Youth program, and the University Affiliated program of the Administration of Developmental Disabilities -- a program which funds pediatric AIDS clinics at university hospitals.

CARE AND SERVICES -- INSERT #3 page 33

Social and Support Services

The increasing incidence of HIV/AIDS calls for a corresponding increase in those services which will help ensure stability, dignity, and appropriate care for all persons with HIV/AIDS.

counseling and testing, medical care, and educational services for medically underserved persons with the goal reducing HIV-related illness. Title IV seeks to increase the availability of care and services for women, infants, children, and youth in a community-based family-centered system of care. HRSA also provides primary care to persons living with HIV through its Community Health Centers and Maternal and Child Health Programs. Housing assistance is provided by the Department of Housing and Urban Development (HUD) through their Housing Opportunities for Persons with AIDS (HOPWA) and other programs.

INSERT #2

Opportunities for Progress

The challenge before us today, especially in light of the restricted fiscal environment, is to ensure that persons living with HIV receive the care they need so they may have the opportunity to live productive lives. To achieve this, AIDS care and service programs must build upon past successes, continue to improve prioritization efforts, improve accountability, and increase the cost-effectiveness of services they provide.

The Health Care Safety Net. We must continue to adequately fund the program that is the cornerstone of care -- Medicaid. Medicaid is the lifeline of support to millions of Americans. It provides access to doctors, hospitals, treatments, and home care -- the services that allow people to live longer more productive lives. Present Congressional plans to cut the Medicaid program overall by $169 billion and turn it into a block grant in effect reverses this Nation's 30 year National commitment to the poor and those in need. Cutting Medicaid to this level would cut the lifeline for millions of Americans, including those living with HIV and AIDS. Maintaining this program in a viable format must be a National priority.

With the potential cuts in Medicaid and welfare, the importance of the public health safety net increases for all vulnerable populations -- disproportionately so for people with AIDS. This will require several responses. First, no one Federal program will be able to absorb the unmet need that may be created by proposed changes to the Medicaid, Medicare and welfare programs. All Federal programs, along with state and local organizations, must share the responsibility for serving and caring for people with AIDS. This must include the full integration of HIV-related care into programs that serve the needy, such as community health centers. Second, it is important that programs such as those funded under the CARE Act receive sufficient funding so as to maintain the safety net. In addition, AIDS programs must do a better job of prioritizing what services they can provide -- and

Federal agencies must assist grantees in this regard. Treatment and primary care must come before ancillary services. And finally, the shift to managed care will have implications for programs such as the Ryan White Care Act programs. As this approach becomes more common, HRSA will need to provide more technical assistance to prepare grantees to work within a managed care structure.

Insert #3 Social and Support Services

Integrated Continuum of Care. Many health care providers believe that one of the most potentially effective approaches to treating HIV positive persons, in addition to reducing the spread of infection, lies in providing people access to an integrated continuum of health care services. This includes counseling and testing, comprehensive health care, home health care, and access to substance abuse treatment and prevention services.

One of the most powerful methods of recruiting people into primary care is knowledge of serostatus -- persons who know they are HIV positive are more likely to seek health care. Counseling and testing services can serve as a gateway to this care. Unfortunately, the majority of Americans do not know whether or not they are HIV positive. There is a need to develop better outreach education in order to encourage people to come in for counseling and testing and link them to appropriate services as needed. Without the linkage of testing to medical care, the opportunity to prolong life is lost.

Linking an HIV positive person with care also provides an opportunity education so they can adopt behaviors which may reduce their chances of infecting others. This in part means offering addiction treatment to assist persons in stopping risky behaviors. It also means offering pregnant women information about and access to AZT during pregnancy to reduce the risk of perinatal transmission. As noted in the Prevention Section of this plan, achieving this level of integration will require active collaborative efforts on the part of individual physicians, nurses, other clinicians, managed care plans, medical schools, and professional organizations in addition to local and Federal governments.

Housing Services. Housing is also an important element in the effort to provide comprehensive care for persons living with HIV. It is the foundation upon which any program of care or services must be built. Without stable housing, a person with HIV/AIDS has diminished access to programs and services and a diminished opportunity to live a productive life. It is estimated that up to 50 percent of persons living with HIV and AIDS will become homeless or are at risk for becoming homeless during the course

FDA

0094208

REVISION

HOLD THIS PAGE

B vitamins (thiamin, riboflavin, and niacin) that are required to be present in enriched farina.

2. Corn and Rice Products

a. Enriched corn grits. No specific comments were received regarding the addition of folic acid to enriched corn grits. Thus, as proposed, FDA is amending § 137.235 to require fortification of enriched corn grits with the same level of folic acid as that established for enriched wheat flour products, such that each pound of the food would contain at least 0.7 mg of folic acid. FDA is also establishing the proposed upper limit for folic acid fortification of 1.0 mg/lb, which is approximately 50 percent higher than the minimum of 0.7 mg/lb, as it has done for the other B vitamins (thiamin, riboflavin, and niacin) that are required to be present in enriched corn grits.

The agency notes that it published a proposed rule in the FEDERAL REGISTER of October 13, 1995 (60 FR 53480), that would revoke the standard of identity for enriched corn grits. If comments to that proposal support revocation of this standard of identity, the provisions set forth in this final rule for enriched corn grits will also be revoked.

b. Enriched corn meals. No specific comments were received regarding the enrichment of corn meal products with folic acid. Thus, as proposed, FDA is amending the standard of identity in § 137.260 to provide for a minimum folic acid level that is consistent with that established for enriched flour, such that each pound of the food contains 0.7 mg. Because corn meal

OPTIONAL FORM 99 (7-90)

FAX TRANSMITTAL | # of pages ▶

To JOHN GALLIVAN	From KEN SMITH
Dept./Agency DHHS	Phone #

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Agency for Health Care Policy
and Research
Rockville MD 20852

FEB 23 1996

FROM: Administrator

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

TO: Director, Office of National AIDS Policy

This is in response to your request for review and comment on the above referenced document.

AHCPR staff have reviewed the text of the draft National Strategy for HIV and AIDS, and find it to be a comprehensive and detailed document which will provide a context for initiatives of the entire Federal government in combatting the HIV/AIDS epidemics.

Our technical comments follow:

- Regarding the reference to the ability of primary care physicians to detect HIV-related findings, I suggest modification of the existing language: "...primary care physicians miss significant HIV-related symptoms during patient examinations..."; to read: "...primary care physicians may miss important HIV-related physical findings during patient examinations." The nature of the study population mitigates against such a broad conclusion as stated in the submitted draft. (See article attached)

- The name of the senior author on the endnote 22 (p. 46) is Paul G. Ramsey (not Ramwey).

- The sentence on page 40, line 11: "Other research indicates that a disturbing number of clinicians are not aware of or do not use universal precautions in the course of routine patient care." needs revision. It should read: "Other research indicates that a large number of clinicians do not use universal precautions in the course of routine patient care." The reference for this statement (endnote 23) is: Colombotos J, Messeri P, McConnell MB, 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, attached).

The information in the appendix has been reviewed and confirmed or updated as indicated.

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

Clifton R. Gaus, Sc.D.

Attachments

RESEARCH

Agency: Agency for Health Care Policy and Research

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

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

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

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

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

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

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

Descriptions: HIV Costs and Service Utilization Study (HCSUS)

FY 95: $4,000,000
FY 96: $3,400,000

Populations Served: HIV-infected individuals receiving treatment.

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

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

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

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

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

Descriptions: Women's Interagency HIV Study (WIHS)

FY 95: 60,000
FY 96: 0

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

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

Unmet Need: None.

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

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

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

Descriptions: Multicenter AIDS Cohort Study (MACS)

FY 95: 65,000
FY 96: 0

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

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

Unmet Need: None

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

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

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

Descriptions: HIV Epidemiological Research Study (HERS)

FY 95: 50,000
FY 96: 50,000

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

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

Unmet Need: None.

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

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

To examine any substitutions of formal for informal home care.

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

Abstract data from Medicaid claims.

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

FY 95: 295,918
FY 96: 39,455

Populations Served: Medicaid recipients with AIDS in New Jersey.

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

Unmet Need: None.

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

Action Steps: Analyzed Medicaid claims and eligibility data from New York State Medicaid files. Completed.

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

FY 95: 392,103 (from FY94 funds)
FY 96:

Populations Served: New York State Medicaid recipients.

Constituency Involvement: N/A

Unmet Need: None.

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

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

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

FY 95: 527,497
FY 96: 479,952

Populations Served: HIV-infected population in Maryland.

Constituency Involvement: N/A

Unmet Need: None.

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

Action Steps: Analyze Medicaid claims and eligibility data, supplemented with AIDS Registry data. To be completed in FY96.

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

FY 95: 110,704 (from 1994 funds)

FY 96: 0

Populations Served: New Jersey Medicaid recipients.

Constituency Involvement: N/A

Unmet Need: None.

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

Action Steps: Formulate statistical models and associated computer software.

Descriptions: Developing Econometric Models to Estimate AIDS Costs.

FY 95: 248,126
FY 96: 8,002

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

Constituency Involvement: N/A

Unmet Need: None.

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

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

Descriptions: Determinants of Physicians' AIDS-Related Practice Behavior

FY 95: 216,054 (from 1994 funds)
FY 96: To be completed during FY96

Populations Served: Persons with AIDS.

Constituency Involvement: Physicians

Unmet Need: None.

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

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

Descriptions: Outcomes of Hospital Dedicated AIDS Units

FY 95: 180,649
FY 96: 214,086

Populations Served: 1300 patients receiving services in study hospitals.

Constituency Involvement: N/A

Unmet Need: None.

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

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

Descriptions: Hospital Cost and Utilization Project

FY 95: 500,000
FY 96: 284,164

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

Constituency Involvement: N/A

Unmet Need: None.

PREVENTION

Agency: Agency for Health Care Policy and Research

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

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

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

Descriptions: Demonstrating Computer Support Impact on AIDS Patients

FY 95: 704,655
FY 96: 36,577

Populations Served: 300 volunteers with advanced HIV infection.

Constituency Involvement: Persons with HIV.

Unmet Need: None.

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

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

Descriptions: Cost-Effectiveness of Preventing AIDS Complications.

FY 95: 346,420
FY 96: 19,731

Populations Served: Persons with HIV.

Constituency Involvement: N/A

Unmet Need: None.

TRANSLATION OF SCIENCE INTO PRACTICE

Agency: Agency for Health Care Policy and Research

Goal: To expedite the dissemination of data from research.

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

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

Descriptions: AIDS Treatment Information Service

FY 95: 75,000
FY 96: 75,000

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

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

Unmet Need: N/A

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

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

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

FY 95: 30,000 (to AIDS clearinghouse)
FY 96: 30,000 (to AIDS clearinghouse, proposed)

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

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

Unmet Need: NA

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

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

Descriptions: Effective Strategies of AIDS Programs in San Francisco.

FY 95: 198,883 (from 1994 funds)
FY 96: 0

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

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

Unmet Need: N/A

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

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

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

FY 95: 15,000
FY 96: 50,000

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

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

Unmet Need: NA

Brief Report

Ability of Primary Care Physicians to Recognize Physical Findings Associated With HIV Infection

Douglas S. Paauw, MD; Marjorie D. Wenrich, MPH; J. Randall Curtis, MD, MPH; Jan D. Carline, PhD; Paul G. Ramsey, MD

Objective.—To assess the ability of primary care physicians to identify physical findings associated with human immunodeficiency virus (HIV) infection.

Design.—Standardized patient examination.

Participants.—A total of 134 general internists and family practitioners were randomly selected after stratifying by year of medical school graduation, specialty, and experience caring for patients with HIV infection.

Main Outcome Measures.—Recognition of physical findings of Kaposi's sarcoma, oral hairy leukoplakia, and diffuse lymphadenopathy.

Results.—Despite being directed by presenting histories to sites of prominent physical abnormalities, only 23 (25.8%) of 89 physicians evaluating a patient with Kaposi's sarcoma and 22 (22.7%) of 97 physicians evaluating a patient with oral hairy leukoplakia detected and correctly diagnosed the abnormalities. Twenty-three (17%) of 133 physicians detected diffuse lymphadenopathy in a patient complaining of fatigue, fever, and arthralgias. Physicians with the most experience treating patients with HIV infection more frequently identified oral hairy leukoplakia, but HIV experience did not influence identification of Kaposi's sarcoma or detection of lymphadenopathy. There were no differences between general internists and family practitioners or among physicians by year of medical school graduation in identifying the three physical findings associated with HIV infection.

Conclusions.—Primary care physicians may frequently miss important physical findings related to HIV infection during patient examinations.

(*JAMA.* 1995;274:1380-1382)

SEVERAL physical findings are strongly associated with human immunodeficiency virus (HIV) infection. Kaposi's sarcoma (KS), a rare tumor in individuals who are not HIV infected, is the most common tumor in patients who are HIV-positive,[1-3] and the presence of KS strongly suggests HIV infection. Oral hairy leukoplakia (OHL) is also strongly associated with HIV infection.[4-6] In a study of 155 patients with OHL, all were found to be HIV infected or at risk for HIV disease.[6] Diffuse lymphadenopathy, although associated with many diseases, is a common finding in HIV-positive individuals.[7] In some patients, these or other physical findings may be the initial manifestations of HIV infection in otherwise asymptomatic individuals. However, little is known about physicians' skills at identifying physical findings commonly associated with HIV infection.

This study used standardized patients to assess the ability of primary care physicians to identify three common physical findings associated with HIV infection: KS, OHL, and diffuse lymphadenopathy. Standardized patients are individuals trained to enact a specific case presentation and to evaluate physicians' performance.[8,9] Use of standardized patients permits assessment of physicians' skills while controlling the patient presentation.

Methods

As part of a larger study using standardized patients,[10] physicians came to a university clinic and saw as many as 16 standardized patients during 1 day of testing. Standardized patients presented a variety of symptoms and physical findings. Each standardized patient received at least 25 hours of training concerning specific medical histories to present, providing consistent responses to questions from physicians, and evaluating physicians' performance in history-taking skills, physical examination, and counseling using objective criteria. Individuals who had prominent physical findings were selected for the patient roles, and their presenting histories were designed to direct physicians to the anatomic areas where the physical findings were located. The patient with OHL told physicians that he had a sore throat and also had noticed white spots on his tongue. On oral examination, the patient had white adherent plaques located on the lateral aspect of his tongue (Figure 1). The patient with KS had lesions on his left ear (Figure 2) and right shoulder. He gave a history of a resolving left earache and a painful right shoulder. The KS lesion on his right shoulder was 1×2 cm, purple, and had sharp margins. The patient with diffuse lymphadenopathy presented with a history of persistent fatigue, fever, and arthralgias and described joint pain in his knees, elbows, and shoulders. He had enlarged lymph nodes greater than 1 cm in diameter in the posterior cervical chains, anterior cervical chains, preauricular and postauricular areas, and axillae bilaterally. All physical findings were evaluated and their presence was agreed on by three physicians with considerable clinical experience in management of patients with HIV infection.

Two standardized patients had cardiac murmurs related to aortic insufficiency, and performance of physicians in detecting these murmurs was evaluated as a comparison with detection of HIV-related findings. The standardized patient with lymphadenopathy had a diastolic murmur related to aortic insufficiency resulting from childhood rheumatic fever. A fourth patient without HIV infection also had a diastolic murmur due to aortic insufficiency and told physician-subjects that he had a resolving upper respiratory infection and pleuritic chest pain. Both patients with diastolic murmurs also had systolic murmurs. These patients were examined by cardiologists and general internists prior to the standardized patient examination, and the underlying causes of the murmurs were confirmed by echocardiography. Both murmurs were graded as being at least III/VI.

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DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

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NOTE TO SUSAN GRIFFITH

Emmett Chase, M.D., National AIDS Program Coordinator, Indian Health Service (IHS), reviewed the draft National Strategy for HIV and AIDS report and provided the following comments:

Agreement with content of report as is.

Referencing the IHS appendix, Unmet Need: is unknown at this time.

Suggest replacing the word **activates** with **dissemination**.

Thank you for the opportunity to review this important document.

W. C. VANDERWAGEN MD

W. Craig Vanderwagen, M.D.
Acting Associate Director
Office of Health Programs

Identification of Physical Findings Associated With Human Immunodeficiency Virus Infection

Standardized Patient's Physical Finding	Physicians Who Saw Standardized Patient, No.	Physicians Who Detected Abnormality, No. (%)*	Physicians Who Correctly Diagnosed Abnormality, No. (%)†
Kaposi's sarcoma	89	42 (47.2)	23 (25.8)
Oral hairy leukoplakia	97	54 (55.7)	22 (22.7)
Diffuse lymphadenopathy	133	23 (17.3)	Not applicable

*Detection of abnormalities was assessed through physicians' responses to a written questionnaire completed after seeing each standardized patient concerning pertinent physical examination findings, including abnormalities and important negatives. Accepted responses included any mention of presence of skin or mucocutaneous lesions for the dermatologic cases and any mention of lymphadenopathy for the patient with fatigue and weight loss.

†Correct diagnosis of Kaposi's sarcoma and oral hairy leukoplakia were determined from physicians' responses to a written questionnaire completed after seeing each standardized patient concerning the most likely diagnostic considerations for each patient.

nificant differences in identifying OHL or KS by specialty or by medical school graduation year, and there were no differences by any of the physician variables in detecting lymphadenopathy.

For the patient with arthralgias and fatigue, 75 physicians (56.4%) described a diastolic murmur or aortic insufficiency murmur. Among 58 physicians who did not correctly identify this murmur, 25 (43%) described only a systolic murmur, 11 (19%) did not mention the murmur, and 22 (38%) mentioned the presence of an undifferentiated murmur or misidentified the murmur. A total of 77 physicians (57.5%) described a diastolic or aortic insufficiency murmur in the patient with pleuritic chest pain. Among the 57 physicians who did not correctly identify this murmur 25 (44%) described a systolic murmur, 12 (21%) did not mention a murmur, and 20 (35%) mentioned the presence of an unspecified murmur. Of the 133 physicians who evaluated both patients with diastolic murmur, 51 (38%) correctly identified both murmurs, 33 (25%) did not correctly identify either murmur, and 49 (37%) identified one of the murmurs correctly.

Seventy percent of the internists identified the murmur for the patient with arthralgias and fever compared with 44% of family practioners ($P=.004$), and 70% of internists identified the murmur for the patient with pleuritic chest pain compared with 47% of family practitioners ($P=.009$). For the patient with pleuritic chest pain, 23 (77%) of 30 physicians who graduated medical school between 1967 and 1974 correctly identified the murmur compared with 29 (50%) of the 58 physicians who graduated between 1975 and 1981, and 25 (54.3%) of 46 physicians who graduated between 1982 and 1988 ($P<.05$).

Comment

Human immunodeficiency virus infection is a disease with cardinal physical findings, and early identification of HIV infection is important for directing treatment that can reduce morbidity. Yet there is ample evidence that preventable morbidity and mortality occur in individuals with undiagnosed HIV infection, as evidenced by low CD4 cell counts at diagnosis,[13] presentation of *Pneumocystis carinii* pneumonia at the time of HIV diagnosis,[14] and hospital admissions for preventable conditions among patients with previously undiagnosed HIV.[15] Inadequate history-taking skills associated with assessment of risk for HIV infection have been documented,[16-18] but physicians' ability to identify physical signs associated with HIV disease had not been studied.

In this study, we examined primary care physicians' ability to recognize three common findings associated with HIV infection: KS, OHL, and diffuse lymphadenopathy. The physicians frequently missed the three HIV-related physical findings and did not make the associated diagnoses.

Among physicians who performed physical examinations on the patients with KS and OHL, approximately half did not detect the lesions as physical examination abnormalities, even though they were alerted by histories to the lesion sites. Among physicians who did describe the lesions, approximately half did not correctly diagnose the lesions based on physical examination. Among all physicians seeing these two patients, approximately three fourths did not correctly detect and identify each lesion. For the patient with diffuse prominent lymphadenopathy, few physicians (17%) detected the abnormality. In comparison, more physicians detected and correctly identified prominent diastolic murmurs. However, 40% or more of physicians either did not detect each murmur or incorrectly identified the type of murmur. These data indicate deficiencies in HIV-related physical diagnosis skills among primary care physicians and also suggest more general deficiencies at physical diagnosis.

Experience with HIV-infected patients appeared to influence the ability to recognize OHL, but not KS or lymphadenopathy. Given the small number of cases studied, however, the power to detect differences in performance based on training experience and other variables is low. Prior experience with HIV infection and other variables may have a greater impact on performance than suggested by the limited number of cases in our study. This study is also limited by the voluntary nature of physician participation. Physicians who volunteer to participate in a study related to clinical skills may be more confident in their skills and perform better than physicians who do not volunteer. Therefore, the findings reported here may overestimate performance among practicing primary care physicians.

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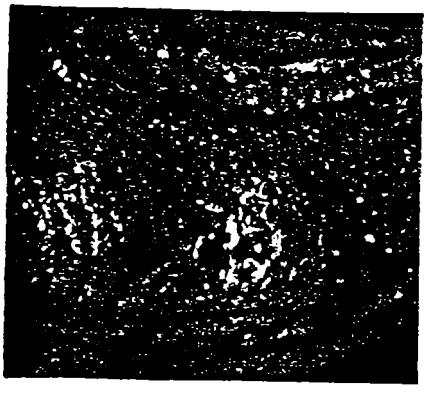

Figure 1.—White, adherent plaques of oral hairy leukoplakia located on the lateral aspect of the tongue

Figure 2.—Distinct, raised reddish-purple lesion of Kaposi's sarcoma on the superior aspect of the helix.

Physical signs were verified by a clinician weekly before the standardized patient sessions to ensure that the signs were present and stable. Because of illness and absences among the standardized patients, not all participating physicians saw all standardized patients.

Primary care physicians (general internists, family practitioners, and general practioners) from Washington, Alaska, Montana, Idaho, and Oregon identified in the *American Medical Association Directory* were recruited by mail. Recruitment methods are documented elsewhere.[11] The study was presented to potential subjects as a continuing medical education course in conjunction with a research project to document primary care practice patterns and clinical skills. Physicians were informed that the standardized patients would present histories and physical findings related to a broad range of diseases. Human immunodeficiency virus infection was listed among diseases that might be presented to the physicians. Physicians were not informed that one focus of the study was identification of physical signs related to HIV infection. The study design was approved by the University of Washington Human Subjects Review Committee, and physicians gave informed consent for participation.

Entry criteria for physician-subjects included spending at least 50% of professional time providing primary care, graduation from medical school in 1967 or later, and specialty in internal medicine, family practice, or general practice. Power calculations indicated that study of 120 physicians would provide sufficient power to detect differences in performance on key variables across a large number of cases; a slightly larger number was selected to compensate for possible dropouts. Among 599 interested and eligible physicians, 134 were randomly selected to participate after stratifying by prior experience with HIV-positive patients, year of medical school graduation, and specialty in either internal medicine or family medicine.

For each patient, physicians had 20 minutes to perform a focused history and physical examination. For these cases, physicians spent a mean of 14 minutes (median, 15 minutes) with each patient. After evaluating each patient, the physicians answered written questions concerning the history and physical examination, diagnostic work-up, differential diagnosis, and management plan. These responses provided the information that would be available in an office record, but also prompted the physicians to list any physical abnormalities that they detected.

Detection of each physical finding by a physician was determined from the written information completed by physicians concerning physical examination findings pertinent in developing a diagnosis, other physical examination abnormalities, and important negative findings. Acceptable responses included any mention of presence of lesions for the KS and OHL cases and any mention of lymphadenopathy for the patient with fatigue, fever, and arthralgias. Correct diagnoses of KS and OHL were determined by responses to a question for each case concerning the most likely diagnostic considerations.

Group comparisons were performed by the experience of the physician treating patients with HIV infection, board-certified specialty, and year of medical school graduation. An overall variable that combined the physician's training and practice experience with treating HIV-infected patients was developed from measures related to medical school experience, residency experience, and self-reported practice-based experience. Physicians were divided into those with least experience (n=57), moderate experience (n=47), and most experience (n=30) with treating HIV-infected patients from the three sources. By board-certified specialty, there were 66 general internists and 60 family practitioners, with eight noncertified physicians excluded from these analyses. By medical school graduation year, 30 physicians graduated between 1967 and 1974, 58 graduated between 1975 and 1981, and 46 graduated between 1982 and 1988.

Group comparisons were performed for the percentage of physicians who correctly identified each physical sign among all physicians seeing each patient. For KS and OHL, comparisons were performed of the percentage of physicians who correctly diagnosed the lesion. For the patient with lymphadenopathy, comparisons were performed of the percentage of physicians detecting any lymphadenopathy. For patients with diastolic murmurs, comparisons were made of the percentage of physicians who described a diastolic murmur or mentioned an aortic insufficiency murmur in the differential diagnosis.

The Mantel-Haenszel test for linear association[12] (χ^2 for trend) was used to compare performance in detecting or identifying each physical sign by the experience of the physicians treating HIV-infected patients and year of medical school graduation. The χ^2 analyses were used to assess performance by board-certified specialty. For all analyses, the α level for a significant difference was set at $P<.05$.

Results

Despite being directed by the presenting history to the lesion sites and despite prominent lesions, only 42 (47.2%) of the 89 physicians who saw the patient with KS noted the presence of any abnormality, and only 54 (55.7%) of the 97 physicians who saw the patient with OHL mentioned the mouth lesion as a physical examination abnormality (Table). Among the physicians who detected an abnormality, many did not provide the correct diagnosis (19 [45%] of the 42 physicians who noted the presence of lesion in the patient with KS and 32 [59%] of the 54 physicians who noted the presence of a mouth lesion in the patient with OHL). Thus, among all physicians seeing each patient with a lesion, approximately one quarter both detected and correctly identified the lesion (Table). Among physicians who detected but did not correctly identify these two abnormalities, the most frequent diagnosis for the patient with KS was a lesion of unknown etiology (n=11), and the most frequent diagnosis for the patient with OHL was oral candidiasis (n=18). Only 23 (17.3%) of the 133 physicians performing a physical examination on the patient with prominent diffuse lymphadenopathy mentioned lymphadenopathy when asked about physical examination abnormalities.

Eleven (46%) of the physicians with the most training and practice experience in treating patients with HIV infection correctly identified OHL compared with five physicians (16.7%) with moderate experience and six physicians (14%) of physicians with the least experience ($P=.007$). There were no sig-