

FOIA MARKER

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

OA/ID Number: 9006
FolderID:

Folder Title:
Strategy - Emails

Stack:	Row:	Section:	Shelf:	Position:
S	66	5	9	1

Archive Files -- National AIDS Strategy

BOX 5 OF 6

Emails

HHS Comments

ONDCP Comments

Budget Information

Draft, August 7, 1996

Printers Copy

NIH Comments

OMB Comments

Printers Copy

"Promises" Summary

GPO

Crosswalk with PACHA Recommendations, Fall 1006

Thank You to President's Advisory Council on HIV and AIDS (PACHA)

NAS for Community Review

Community Comments

ONAP and Community Comments

POTUS Letter for NAS

Figures

ONAP Comments

OMB Comments

Crosswalk of Community Comments

PACHA Conference Call

PACHA Comments

NAS Mailing

NAS Draft

ONDCP

NAS Draft for ONAP Review, 10-31-96

Community Meetings/POTUS Event

IDTF Closure Memo

9006
ENCLOSURES FILED OVERSIZE ATTACHMENTS
NANA 6515

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

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

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

FACSIMILE COVER SHEET

TO: Barbara Roberts

FAX NUMBER: 395-16744

FROM: Jane Samille

DATE: 9.5.96

PAGES INCLUDING COVER SHEET: 2

COMMENTS:

August 23, 1996



Health Division



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

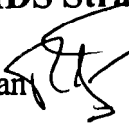
Please route to:

For the File

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

Subject: **National AIDS Strategy Document**

With informational copies for
HPS and HD Chrons, NEM
J. Levi

From: Richard Turman 

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

The Office of National AIDS Policy (ONAP) is seeking clearance by COB, Friday, August 23rd, for the attached document, "National Strategy for HIV and AIDS." Given that OMB did not receive a complete copy of this document until Tuesday evening (8/20) of this week, OMB policy officials did not have sufficient time to carry out a complete policy review of the document, as would be the norm with such documents.

However, based on a conversation that Nancy-Ann Min had with Jeff Levi of ONAP where he advised that both he and Patsy Fleming personally wrote the document, the Health Division is clearing the document with the attached staff comments.

In the future, we have requested that ONAP ensure that OMB be given additional lead time to review documents of such length and visibility.

Attachment

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

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

Phone: 202-632-1090

Fax: 202-632-1096

FACSIMILE COVER SHEET

TO: Jeremy Ben Ami

FAX NUMBER: 456 2216 7028

FROM: Jane Saville

DATE: 9/5/96

PAGES INCLUDING COVER SHEET: 3

COMMENTS:

Jeremy -

This is the fax I referred to in
my email of today.

Jane



EXECUTIVE OFFICE OF THE PRESIDENT
OFFICE OF NATIONAL DRUG CONTROL POLICY
Washington, D.C. 20503

August 27, 1996

*BR/PS - keep
Thanks - keep
me informed*

MEMORANDUM FOR THE CHIEF OF STAFF

THROUGH:

RICIA MC MAHON
JOHN CARNEVALE
DAN SCHECTER

FROM:

BARBARA T. ROBERTS

SUBJECT:

NATIONAL AIDS STRATEGY-8/20 DRAFT FOR REVIEW

July 22, 1996 ONDCP submitted text for inclusion in the National AIDS Strategy. August 20, 1996 ONDCP received a draft of the AIDS Strategy for review and sign-off. Copies were circulated to ONDCP staffers Mc Mahon, Gregrich and Carnevale for comment. Enclosed is feedback received. These comments should be forwarded to the AIDS Office for consideration of a revision of the draft.

In general, the draft reflects only partial inclusion of the ONDCP statement submitted (see Enclosure, 1). Although this may have been an editorial decision on the part of the AIDS Office, the resulting statement (see p.10) does not provide the full scope of demand and supply initiatives undertaken by this Office. ||

Another concern is the lack of inclusion in the document of marijuana, alcohol and tobacco as drugs whose effects also contribute to the risk of acquiring HIV. All illicit drugs (alcohol and tobacco by virtue of prohibition of use, by law, by underage youth) carry associated consequences. Each of these drugs alter mood and lower inhibitions which can lead to poor decision making, i.e., engaging in indiscriminant sex. In addition to the obvious inclusion of intravenous drug use, ONDCP urges the AIDS Office to revise the draft to include the use of the aforementioned drugs as having associated risk factors as well.

The needle exchange statement is circular and draws a conclusion not altogether borne of the current research. Needle exchange research, to date, is limited and cannot be termed "successful." ONDCP strongly urges rewording of this statement (see p. 13) to more accurately reflect the state of needle exchange studies, accompanied by the pros and cons of research results.

Page 2.

Finally, the AIDS Office has requested ONDCP to sign-off on the draft and, thus, clear it for publication. The Federal regulatory clearance process involves submission of a document to the Office of Management and Budget (OMB), first. OMB, in turn, fields the document to appropriate Federal agencies for comment and feedback, before it issues an official clearance statement. It does not appear OMB has cleared this document. The AIDS Office will need to clarify the issue of the clearance process followed before ONDCP can officially sanction a final draft.

Enclosures.: 1) July 22, 1996 ONDCP Memo.
2) ONDCP Staff Comments to AIDS Strategy Draft

cc: Dir., National AIDS Policy Office

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

11-Sep-1996 04:03pm

TO: Ursula Sanville

FROM: Patsy Fleming
 AIDS Policy Council

SUBJECT: FYI

EXECUTIVE OFFICE OF THE PRESIDENT

11-Sep-1996 12:07pm

TO: Jeremy D. Benami

FROM: Patsy Fleming
AIDS Policy Council

CC: Jeffrey Levi

SUBJECT: RE: Circulating the draft plan

I think the Council worked out a solution to a serious problem. The problem was that most council members felt they could not speak positively about the strategy in its current form. They requested a period of time before distribution to the community during which council members will submit comments to us. Comments must be submitted by November 15. That gives us a month to make changes we feel are appropriate and circulate those changes to the agencies and get the next draft ready to present to the council at their next meeting (Dec. 15, 16, 17). This draft would go out to the community at the same time.

During this review period, the members said they would not give the draft strategy to anyone (!) but that if it somehow became public, or the community became upset because they are not getting it until December, they would say 1) that they cannot comment on the draft because it is still under review and 2) that the document is not being released because they requested time to review it and submit comments.

I believe the draft strategy is legally a "public document" since it was distributed at a public meeting. However, we are confirming this and whether we would have to respond to any requests from the public or media for copies.

I think this is the best alternative we could have been given. We will respond to any crises as they come up.

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

05-Sep-1996 11:02pm

TO: Jeffrey Levi

FROM: Jeremy D. Benami
 Domestic Policy Council

SUBJECT: strategy

The only email I got re the strategy is one from Jane that says she needs help with ONDCP.

I never got a final copy of the strategy and no update on the HHS contacts.

If I am going to be helpful to you guys, you need to keep me posted.

Can I see the document that went to HHS?

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

06-Sep-1996 09:20am

TO: Jeremy D. Benami

FROM: Jeffrey Levi
 AIDS Policy Council

SUBJECT: RE: strategy

we'll get that over right away -- sorry. There should have been a subsequent e-mail saying all is resolved with HHS -- and that ONDCP has signed off now that OMB has agreed to the numbers.

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

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

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

FACSIMILE COVER SHEET

TO: PATSY FLEMING

FAX NUMBER: 813-229-⁵⁰²²~~5322~~

FROM: JANE SANVILLE

DATE: 8.15.96

PAGES INCLUDING COVER SHEET: 8

COMMENTS:

Hello Patsy - Here's the re-worked prevention
section. J.

DRAFT OF REWORKED PREVENTION SECTION:

- SHORTER
- PUNCHIER HEADINGS
- ADDED SECTION ON POPULATIONS AT INCREASED RISK, INCORPORATED 'PRISONERS' TEXT INTO THIS SECTION

=====

A. PREVENTION

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

President Clinton, December 5, 1995, to the White House Conference on HIV and AIDS.

1. Record of Accomplishment

Since the epidemic began, the U.S. has made important progress in prevention of HIV infection. In the early years of the epidemic, it was estimated that more than 100,000 Americans were becoming infected with HIV each year. Today, that total is between 40,000 and 60,000 people each year.

Sentinel accomplishments in prevention of HIV have been:

- Identification in 1981 by the Centers for Disease Control and Prevention (CDC) of the first cases of AIDS;
- Identification in 1981 by the Centers for Disease Control and Prevention (CDC) of the risk behaviors associated with HIV infection; and
- Due in part to successful implementation of CDC-sponsored prevention strategies, a slowing in the growth of the epidemic.

Since President Clinton took office in 1993, efforts in HIV/AIDS prevention have been accelerated. The Administration has:

- Increased funding for AIDS prevention by 24 percent;
- Launched the community planning partnership, which empowers local communities to make decisions about the development of innovative prevention efforts;
- Launched the Prevention Marketing Initiative, focusing on the risk to young adults (18 to 25) with frank public service announcements advocating sexual abstinence and, for the first time in the epidemic, the correct and consistent use of latex condoms; and,
- Reorganized AIDS prevention efforts at the Centers for

Disease Control and Prevention to foster greater coordination with efforts to reduce sexually transmitted diseases and tuberculosis.

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

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

The U.S. has also combatted the dual epidemics of HIV and drug abuse. The National Institute on Drug Abuse (NIDA) and the Substance Abuse and Mental Health Services Administration (SAMHSA) support efforts to prevent HIV infection among drug users. The Office of National Drug Control Policy has pursued efforts to counter the problem of substance abuse and its devastating consequences.

There have been advances in integrating primary prevention into health care service systems. The Health Resources and Services Administration (HRSA) and the Department of Veterans Affairs (VA) have encouraged broader access to prevention information through the integration of prevention interventions into primary health care services and through support of early intervention services. 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.

2. *Future Opportunities for Progress*

Significant challenges remain if we are to reach the Nation's prevention goal -- no new infections. To achieve this goal we must:

- Improve our understanding about the major trends in transmission and seroprevalence of HIV transmission;
- Close gaps in scientific knowledge by identifying additional effective prevention models and strategies; and
- Eliminate gaps in HIV prevention program areas.

A. Focusing Prevention Efforts: Improving Understanding of Trends in the Epidemic

Effective prevention interventions begin with sound information about who is at risk. CDC's AIDS case and case death reporting system provides important data for assessing AIDS prevalence and mortality by gender, race/ethnicity, age, and mode of exposure. However, current CDC surveillance systems do not capture sufficient "front-end" information on the incidence and prevalence of HIV prior to an AIDS diagnosis. These data must be collected with appropriate confidentiality protections for the identity of those who are living with HIV.

CDC has initiated efforts to evaluate current data collection efforts and implement necessary changes. The Agency is exploring innovative approaches for collecting HIV incidence information. It has also incorporated data collection design efforts into its community planning process. These initiatives are part of the Agency's implementation of the recommendations set forth in the external review of CDC's HIV prevention strategies¹ and will continue.

B. Designing Better Prevention Programs: Supporting Prevention Research (Footnote c)

We must not *assume* to intuitively know which prevention interventions will work. Our efforts must instead be based on a sound research base. Factors that place individuals at risk for acquiring HIV infection are a complex mixture of behavioral, social, cognitive, and biological influences. Improving our understanding will require closing gaps in scientific knowledge in basic behavioral research, intervention research, and social marketing research.

Basic Behavioral Research. Information provided by basic behavioral research is the foundation for prevention programs. To capitalize on what is known and to improve HIV prevention programs that are targeted to reach diverse populations of Americans, more information on the determinants of HIV-associated sexual and drug-using behaviors is needed. Such data enable scientists to establish theories of behavioral change, which then provide researchers with tools for identifying approaches that may be most effective for an individual or a community.²

Intervention Research. To improve prevention interventions we must learn more about modifying HIV-related behaviors, such as those related to drug use and sex. We need more information on the role of both individuals and communities in HIV prevention, each of whom often adhere to norms that influence personal behavior. We must also intensify the dialogue among HIV-prevention researchers in biomedical,

behavioral, and social science fields if we are to improve the development of effective prevention interventions. And, we must improve the data-sharing and collaborative efforts among Agencies responsible for implementing prevention programs.

Social Marketing Research. Agencies supporting social marketing activities need to build on current knowledge and strengthen efforts to understand barriers to the implementation and replication of promising prevention programs. As these models are developed, community-based organizations will require additional technical assistance and training in order to test those models in a "real-world" setting.

C. Transforming Research into Reality: Strengthening Prevention Programs

For prevention interventions to be effective they must reach people at risk and be responsive to their needs. For individuals to take control of their own lives in fighting the spread of this virus, they must first have the information and skills to protect themselves. And for program planners, it is important to carefully prioritize local efforts based on who infected is and who is becoming infected.

One of the most important innovations in HIV prevention is the creation of community planning. Through this public-private partnership it has been possible to establish joint goals for the prevention of HIV that are responsive to local needs. This process is early in its development and requires continuing significant leadership and technical assistance. Small, new, community-based organizations -- especially those serving minority populations -- often require additional technical assistance in order to compete for available resources. CDC and other Federal Agencies provide such assistance and will continue to do so.

It is crucial that prevention research results be disseminated and incorporated into prevention programs. Models of effective prevention interventions have been developed but often this valuable information is not reaching those people developing, implementing, and evaluating prevention programs. (See Section on Translation of Research Advances into Practice.)

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

First, we need to improve the integration of HIV prevention activities and substance abuse treatment and prevention programs. The epidemics of substance abuse and HIV in this country are

overlapping and highly interrelated, however, many care and prevention service programs for HIV and substance abuse are not optimally integrated. It is vital to continue and strengthen efforts to integrate HIV prevention into current substance abuse programs and integrate substance abuse prevention into HIV prevention.

A key to controlling the spread of HIV among substance abusers is enrollment into drug treatment. Substance abuse treatment is a major form of HIV prevention. Moreover, substance abuse problems that contribute to the spread of HIV are not limited to injecting drug use; use of non-injectable drugs such as alcohol and crack cocaine can adversely influence risk-taking behavior. The efforts of the Office of National Drug Control Policy to motivate Americans to reject illegal drugs and substance abuse are an important element in controlling the epidemic.

Work on these issues has begun and will continue. CDC has initiated State-by-State discussion including meetings with State Legislators and the National Conference of State Legislatures regarding HIV prevention issues. SAMHSA's new "Knowledge Development Application (KDA) Program" will address emerging issues in the fields of substance abuse and mental health, including a focus on HIV and AIDS. CDC, HRSA, NIDA, and SAMHSA are co-sponsoring a national meeting of State and local officials from the fields of public health and drug abuse prevention to develop an action plan that more effectively integrates HIV and substance abuse prevention efforts.

Improving Treatment for Sexually Transmitted Diseases and Tuberculosis. Research has shown that the presence of other sexually transmitted diseases (STDs) can significantly increase the efficiency of HIV transmission, by as much as twenty-fold. Studies have also shown that widespread treatment of STDs in certain communities has led to a 40 percent reduction in new HIV infections in these groups.^{3,4} These data suggest that treating STDs can be a very effective HIV prevention strategy and points to a need for all clinicians to be vigilant in efforts to prevent and treat STDs. NIH-supported research to further understanding of the effect of STD treatment on HIV transmission is underway and will continue.

It is important that Federal and State efforts to reduce the incidence of sexually transmitted diseases (STDs) include an HIV prevention element and that HIV prevention programs incorporate STD prevention and treatment efforts. The traditional model of targeting most STD prevention efforts towards individuals who have already contracted an STD is not necessarily effective for HIV prevention. Linkages between STD and HIV prevention efforts need to be established and, where they do exist, enhanced.

People living with HIV are at very high risk for developing active tuberculosis (TB) disease. Studies suggest that the risk

of developing active TB disease is 7 to 10 percent per year for persons who are infected with both TB and HIV, whereas the risk is 10 percent per lifetime for persons not infected with HIV.⁵ In addition to the health implications for infected persons, there is an increased risk of transmission of TB to household members, health care workers, and other persons having regular contact with a person with active TB.

The newly organized National Center for HIV, STD, and TB Prevention at CDC demonstrates the importance of integrating the interdependent aspects of the epidemic and illustrates the determination to integrate and coordinate HIV, STD, and TB prevention efforts.

Integrating Prevention Into Primary Care. To reach our prevention goal, we must also improve the integration of prevention activities and messages into primary health care services. HIV counseling and voluntary testing often provide an important bridge between HIV prevention and care for many at-risk persons. To assure that all persons seeking HIV testing can have access to such services, CDC's counseling and testing guidelines must acknowledge and address the needs of persons seeking such services, and provide training for personnel at CDC-funded sites.

Incorporating a person's sexual and drug use history when a medical history is taken, offering HIV-related counseling and voluntary testing, and providing prevention education to HIV-positive individuals so they do not infect others is also important. In addition, to reduce perinatal transmission, all pregnant women should be offered HIV counseling and voluntary testing as well as information about and access to AZT. Training should be made available to improve primary care providers' skill, comfort level, and sensitivity in these areas.

Achieving this level of integration requires active collaborative efforts on the part of individual physicians, nurses, other clinicians, managed care plans, medical schools, and professional organizations in addition to State, local, and Federal governments. Presently HRSA's Ryan White Care Act (RWCA), primary care, and professional training programs emphasize the value of integrating prevention into primary care. These are important efforts that will continue.

Preventing Infections in People at Increased Risk. Recent epidemiologic data show that the HIV epidemic continues to spread most rapidly among people who engage in injection drug use and their sexual partners, women, young and minority men who have sex with men, heterosexuals and infants who are infected through perinatal transmission. Those in prison are also at especially high risk for both substance abuse and HIV infection due to the often high prevalence of behaviors that lead to both substance abuse and HIV infection in people entering prison.

It is vital that prevention programs reach those at great risk.

Research has shown that people who are well informed about HIV and substance abuse issues modify their risk-taking behaviors. Federal effort have responded, and will continue to respond, to this need. NIH has set forth guidelines for the inclusion of women and members of minority groups in NIH-sponsored research. CDC has proposed a \$34 million increase in prevention efforts to reach high risk populations such as women, youth, men who have sex with men, and substance abusers. At the community level, it is critical that these trends in the epidemic be considered when prioritizing prevention research and service programs.

Enhancing Program Effectiveness Through Evaluation. It is important to assess the effectiveness of the HIV prevention interventions. Prospectively-set performance measures can be used as a basis for evaluation and program improvement and must become a routine part of all Federally-funded programs. It is only through sound evaluations that we will be able to determine whether our efforts have been effective in slowing the epidemic.

1. External Review of HIV Prevention Strategies by the CDC Advisory Committee on the Prevention of HIV Infection. U.S. Department of Health and Human Services, Public Health Service. June 1994.
2. *AIDS and Behavior: An Integrated Approach*. Judith D. Auerbach, Christian Wypijewska, and H. Keith H. Brodie, Editors. Institute of Medicine. National Academy Press. Washington, DC. 1994.
3. Heiner Grosskurth, Frankc Mosha, James Todd, Extra Mwijarubi, Arnould Clokke, Kesheni Senkoro, Philippe Mayaud, John Chagalucha, Angus Nicoll, Gina ka-Gina, James Newell, Kokuugonza Mugeye, David Mabey, Richard Hayes. Impact of Improved Treatment of Sexually Transmitted Diseases on HIV Infection in Rural Tanzania: Randomized Controlled Trial. *The Lancet*, Vol. 346, August 26, 1995.
4. Maria Wawer, *Science*. 9.08.95, vol. 269, No. 5229
5. Personal communication from CDC Division TB Elimination.

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

15-Aug-1996 09:14pm

TO: Ursula Sanville
FROM: Jeffrey Levi
 AIDS Policy Council

SUBJECT: fyi

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

15-Aug-1996 05:43pm

TO: Jeremy D. Benami

FROM: Jeffrey Levi
 AIDS Policy Council

SUBJECT: RE: research rewrite

thanks for the editing...I will look at this more carefully tonight and also try to get you the rest of the document.

Yes, somehow you lost two parts of the research opportunities. I will retransmit later.

I will look at the contributions vs. accomplishments in research. The distinction is that we want to have in the contributions section something that responds to the argument that we spend too much money on AIDS research, which obviously has a different purpose than the accomplishments section.

The dirty little secret is that we can't claim research on protease inhibitors as one of our accomplishments -- they were done almost exclusively with private research money.

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

15-Aug-1996 09:15pm

TO: Ursula Sanville
FROM: Jeffrey Levi
 AIDS Policy Council

SUBJECT: fyi

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

15-Aug-1996 08:00pm

TO: Jeffrey Levi
FROM: Jeremy D. Benami
 Domestic Policy Council

SUBJECT: RE: research rewrite

re protease - isn't this a national plan, can't we be listing national accomplishments - phrasing isn't these are "federal" accomplishments - it's we the country's accomplishments.

contributions section starts out just hitting the crossover benefits, but by the end it's listing pure AIDS accomplishments. I think the crossover section should be limited to that as a subheading of the accomplishments section.

have fun!!!!

hope this is helpful, I like this iterative editing. At the end of the process we should have a good piece, I think.

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

15-Aug-1996 09:16pm

TO: Jeremy D. Benami
FROM: Jeffrey Levi
 AIDS Policy Council
CC: Ursula Sanville
SUBJECT: RE: research rewrite

we can put something in about protease, by that theory

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

16-Aug-1996 10:23am

TO: Ursula Sanville
FROM: Jeffrey Levi
 AIDS Policy Council

SUBJECT: fyi

EXECUTIVE OFFICE OF THE PRESIDENT

16-Aug-1996 09:11am

TO: Jeffrey Levi
FROM: Jeremy D. Benami
Domestic Policy Council

SUBJECT: RE: rest of strategy

I don't think I got specials pops and eval in the first place - so that's why they are not there. Can you send those pieces too?

I'll work on the remainder of the doc this a.m. and send to you asap.

We should have it done by Monday.

By the way on the intro - I would use the intro Section I to state clearly that the national strategy is driven by "x" goals (4,5,?): (1) No new infections (2) Find a Cure and a Vaccine (3) [Approp service goal], etc. - then the intro frames the document. The President's letter can then say how committed he is to the four goals of the strategy and to meeting the challenges laid out in meeting those goals. Then Section II is the "State of the Epidemic" - then III thru VII are the action sections.

On the credit for protease question - How much more would there be to add to the various accomplishments sections if it were regarded more broadly as "national" achievements rather than federal governments? Is protease an exception or one of many examples??

On needles - can you think of any way to write the para to acknowledge the issue exists - acknowledges that there is controversy (not among researchers or in the AIDS community but in the country at large) and says we need to continue to work this through as a country??? My instincts (which could well be wrong) tell me that total silence might be worse than some sort of statement like this that at least acknowledges the issue exists? Thoughts?

See ya

*Jeff -
have doc
on this*

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

16-Aug-1996 10:24am

TO: Ursula Sanville
FROM: Jeffrey Levi
 AIDS Policy Council

SUBJECT: fyi

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

16-Aug-1996 10:21am

TO: Jeremy D. Benami
FROM: Jeffrey Levi
 AIDS Policy Council

SUBJECT: RE: rest of strategy

yes, we can do something with protease as national
accomplishments.

i'll think about needles over the weekend -- there may be a way of
doing this (tho will ONDCP clear the document?)

yes, we should have this done by Monday so it can go to HHS -- we
should talk on monday about how to push it through there quickly.

i'm out of computer contact for the rest of the day.

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

14-Aug-1996 10:00pm

TO: Ursula Sanville

FROM: Jeffrey Levi
 AIDS Policy Council

SUBJECT: prevention--my cut

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

14-Aug-1996 07:35am

TO: Jeremy D. Benami

FROM: Jeffrey Levi
 AIDS Policy Council

SUBJECT: redraft, part I

Jeremy--This is the revised prevention section. I have done nothing to the first part -- the new material follows the three goals in opportunities for progress. With a small screen and no printer, I have not been able to format this well -- I just need your sense of whether this is going the right way and if I should continue on research and services -- tomorrow night (or, more accurately, tonight.)

Thanks. jeff

A. PREVENTION

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

President Clinton, December 5, 1995, to the White House Conference on HIV and AIDS.

1. Record of Accomplishment

Since the epidemic began, the Nation has made important progress in prevention of HIV infection. In the early years of the epidemic, it was estimated that more than 100,000 Americans were becoming infected with HIV each year. Today, that total is between 40,000 and 60,000 people each year.

Sentinel accomplishments in prevention of HIV include:

- ? Identification in 1981 by the Centers for Disease Control and Prevention (CDC) of the first cases of AIDS;
- ? Identification in 1981 by the Centers for Disease Control and Prevention (CDC) of the risk factors associated with HIV infection; and

- ? Due in part to successful implementation of CDC-sponsored prevention strategies, a slowing the growth of the epidemic.

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

- ? Increasing funding for AIDS prevention by 24 percent;
- ? Launching the community planning partnership, which empowers local communities to make decisions about the development of innovative prevention efforts;

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

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

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

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

There have been advances in integrating primary prevention into health care service systems. The Health Resources and Services Administration (HRSA) and the Department of Veterans Affairs (VA) have encouraged broader access to prevention information through the integration of prevention interventions into primary health care services and through support of early intervention services. 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.

2. Future Opportunities for Progress

Significant challenges remain if we are to reach the Nation's

prevention goal -- no new infections. Primary to this progress are efforts to:

- ? Improve our understanding about the major trends in transmission and seroprevalence of HIV transmission;
- ? Close gaps in scientific knowledge, which includes identifying additional effective prevention models and strategies; and
- ? Eliminate gaps in HIV prevention program areas.

doesn't happen later

a. Improving Understanding of Trends in the Epidemic

Understanding who is becoming infected and through what behaviors is critical to designing effective prevention interventions (as well as targeting services resources). Over the course of the epidemic, there have been shifts in the demographics of who is affected by HIV, as discussed in the (previous?) section. CDC's AIDS case and case death reporting system provides important data for assessing AIDS prevalence and mortality by gender, race/ethnicity, age, and mode of exposure. However, this approach does not capture sufficient "front-end" information on the incidence and prevalence of HIV prior to an AIDS diagnosis and thus we lose critical warning signs about new trends in what population groups are affected by HIV and what risky behaviors are increasing.

To address this shortcoming, the CDC is now undertaking a process to improve its surveillance of HIV infection and related diseases: both to address our need to better monitor the course of the epidemic and to provide guidance to community planners regarding the targeting of prevention and service dollars. This can and will be undertaken without compromising the confidentiality of those involved.

b. Research

sure this is true

Effective interventions must be based on sound research findings and evaluations. Prevention and behavioral research did not receive the same priority of funding in the early years of the epidemic as did biomedical research. In the years ahead, the NIH and CDC are both committed to increasing support for basic behavioral research, intervention research, and social marketing research.

↑ as population

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

developing effective interventions.

Intervention research focuses on individual and community level interventions that result in modify sexual and drug using behaviors. While significant work has been accomplished in this area, as this portfolio expands, it will be critical to assess intervention in real world settings that are relevant to the growing number of populations that must be reached by prevention programs. This research should be designed by a broad range of scientists, public health, and community experts to assure its relevance.

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

c. Strengthening Community Programs

Community prevention planning -- one of the key innovations in CDC's prevention programming over the last several years -- is at a crucial stage of development. This public and private partnership has made possible the use of federal funds based on locally designed priorities. We recognize that community planning requires continuing significant leadership from CDC and its partners and a strong commitment of resources that will offer the community planning process the technical assistance it needs to flourish. Successful HIV prevention often depends on small, new community based organizations, many serving minority populations, who often require additional technical assistance in order to successfully compete for available resources. Technical assistance cannot just be around the planning process. It must also include making accessible to community leaders the surveillance, epidemiological and behavioral research discussed above.

d. Program Integration and Collaboration

HIV prevention programs cannot stand apart from other, related public health efforts. Through the coordination efforts of ONAP and HHS's Office of HIV/AIDS Policy, there is an ongoing commitment to increasing the integration of HIV prevention into other program areas that reach individuals at risk for HIV.

HIV transmission is directly related to substance abuse, both directly through needle sharing behavior and indirectly as sex is traded for drugs or drug use impairs judgment and increases risk taking behaviors. Breaking that linkage will require:

? Integration of HIV prevention activities and substance abuse

treatment and prevention programs. In August, 1996, at the request of President Clinton, the Public Health Service agencies jointly co-sponsored a national meeting of State and local officials, researchers, and community experts from the fields of HIV and substance abuse to develop an action plan that more effectively integrates HIV and substance abuse prevention efforts. These agencies are committed to implementing this strategy in the year ahead (assuming we like it).

? Enrolling more substance abusers into drug treatment. Substance abuse treatment is a major form of HIV prevention. This Administration will continue to press for increased funding for substance abuse treatment. Further, through outreach and demonstration programs, SAMHSA and CDC will increase their efforts to bring more individuals into treatment and find more successful interventions to accomplish this end.

? Reducing the availability of illegal drugs. Through the leadership of ONDCP, the Federal government recognizes that substance abuse must be addressed on two fronts: reducing demand for drugs through treatment and prevention programs, and reducing the availability of drugs through interdiction.

place holder for needles???

Another important goal is better integration of HIV prevention into primary care. HIV counseling and testing are an important bridge between prevention and primary care. With new and promising medical interventions available, CDC is committed to improving the return rate of those tested at publicly funded sites and the quality of referral to services for those who test positive. But the linkage must also go in the opposite direction: from primary care to prevention.

Primary care providers must learn to incorporate a person's sexual and drug using history when a medical history is taken, offering HIV-related counseling and voluntary testing, providing prevention education to HIV positive individuals as part of the provider-patient relationship. HRSA's AIDS Education and Training Centers (AETCs) have played a crucial role in giving providers the information and skills they need. The Administration is committed to restoring Congressionally-imposed cuts in the AETC program and giving it a renewed focus to support this goal.

Often primary care is a direct form of HIV prevention. The tremendous medical breakthrough that has been achieved in reducing the chance of perinatal transmission by two-thirds through the use of AZT requires a strong policy of assuring that all pregnant women are counseled and offered HIV testing and that

AZT treatment is available for all who desire it. All federally funded programs reaching pregnant women -- from Medicaid to Ryan White CARE Act grantees to community and migrant health centers -- are required to take part in this effort. We are committed to expanding outreach and assuring appropriate care so that the Congressionally set goal of reducing perinatal transmission by 50 percent by the year 1995 is achieved.

Recent research has confirmed that treatment of sexually transmitted diseases (STDs) other than HIV can reduce the likelihood of HIV transmission. This makes more compelling the need for collaboration between HIV and STD prevention efforts. Similarly, the relationship between tuberculosis and HIV is very strong. People living with HIV are at very high risk for developing active tuberculosis. Studies suggest that the risk of developing active TB is 7-to-10 percent per year for persons who are infected with both TB and HIV, as opposed to 10 percent risk over a lifetime for persons not infected with HIV.¹

In addition to the health implications for infected persons, there is an increased risk of transmission of TB to household members, health care workers, and other persons having regular contact with a person with active TB.

The newly organized National Center for HIV, STD, and TB Prevention at CDC demonstrates the importance of integrating the interdependent aspects of these epidemics. CDC has initiated -- and will aggressively pursue -- efforts to increase collaboration among these programs, including expanding the community planning experiment to cover STD programs.

e. Special Populations

There are certain populations where the HIV epidemic has had a disproportionate impact or where HIV infection rates are rising at a worrisome pace. These include youth (especially young gay men), women, and minorities (especially gay men of color), prisoners, and, as discussed above, substance abusers. While many federally funded HIV prevention activities already target these populations, as part of the President's increased funding request for CDC, \$35 million in new funds will be provided for programs targeting youth, women, and substance abusers.

f. Evaluation

To ensure that prevention programs are actually working -- and so scarce resources are spent on the most effective interventions -- all federally funded prevention activities will routinely include evaluation components. The funding agencies will share widely the knowledge gained about what works and what does not to ensure promotion of best practices in the field. In addition, as part

1. Personal communication from CDC Division TB Elimination.

of the federal government's compliance with the Government Performance and Results Act, CDC and SAMHSA will continue to work with its constituents to develop appropriate performance measures for HIV prevention programs.

MIX OF JL/JAB => EXTRA COPY

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

15-Aug-1996 04:52pm

TO: Jeffrey Levi

FROM: Jeremy D. Benami
 Domestic Policy Council

SUBJECT: prevention section

Here's my next crack at prevention edit. I am almost satisfied with this section. What it still needs, though, is some concrete sense of the 1997 and beyond agenda in some of these areas - you'll see my questions inserted. For instance, if it's a priority to support social marketing research, we need to say what it is we will then in fact do - what are we funding, what actions are we taking, etc.

In Dutch 12 point, this section is now five pages. We're getting there length-wise. I'm moving on to the research section now. Keep em coming!!

let me know what you think of the needle para!!!

A. PREVENTION

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

President Clinton, December 5, 1995, to the White House Conference on HIV and AIDS.

1. Record of Accomplishment

Since the epidemic began, there has been important progress in preventing HIV infection. Early in the epidemic, more than 100,000 Americans were estimated as becoming infected with HIV each year; today, that total is between 40,000 and 60,000 annually.

Sentinel accomplishments in prevention of HIV include:

- o Identification in 1981 by the Centers for Disease Control and Prevention (CDC) of the first cases of AIDS;
- o Identification in 1981 by the Centers for Disease Control and Prevention (CDC) of the risk factors associated with HIV infection; and
- o Due in part to successful implementation of CDC-sponsored prevention strategies, a slowing the growth of the epidemic.

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

- o Increasing funding for AIDS prevention by 24 percent;
- o Launching the community planning partnership -- empowering local communities to make decisions about and develop innovative prevention efforts;
- o Launching the Prevention Marketing Initiative, focusing on young adults (18 to 25) with frank public service announcements advocating sexual abstinence and the correct and, for the first time in the epidemic, consistent use of latex condoms; and,
- o Reorganizing AIDS prevention efforts at the Centers for Disease Control and Prevention to foster greater coordination with efforts to reduce sexually transmitted diseases and tuberculosis.

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

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

The nation has also combatted the dual epidemics of HIV and drug abuse. The National Institute on Drug Abuse (NIDA) and the Substance Abuse and Mental Health Services Administration (SAMHSA) support efforts to prevent HIV infection among drug users. The Office of National Drug Control Policy has pursued efforts to counter the problem of substance abuse and its devastating consequences. *and CDC*

There have been advances in integrating primary prevention into health care service systems. The Health Resources and Services Administration (HRSA) and the Department of Veterans Affairs (VA) have encouraged broader access to prevention information through the integration of prevention interventions into primary health care services and through support of early intervention services. 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. *and HRSA*

2. Future Opportunities for Progress

To reach the President's national prevention goal of no new infections, we face some significant challenges. Our efforts are therefore focused in four areas:

- o Improving understanding of trends in HIV transmission *and surveillance*
 - o Improving scientific knowledge about effective prevention models and strategies *through research and evaluation*
 - o Strengthening community based programs
 - o Integrating HIV and other prevention efforts *Addressing the needs of special populations*
- a. Improving Understanding of Trends in the Epidemic

Understanding who is becoming infected and through what behaviors is critical to designing effective prevention interventions (as well as targeting service resources). As discussed in Section II (?), the demographics of the epidemic have shifted, and effective prevention depends on rapidly understanding these shifts and responding to them.

CDC's AIDS case and case death reporting system provides important data for assessing AIDS prevalence and mortality by gender, race/ethnicity, age, and mode of exposure. However, this approach does not capture sufficient "front-end" information on the incidence and prevalence of HIV prior to an AIDS diagnosis. We,

therefore, miss critical warning signs about new trends in affected populations and increasing risky behaviors.

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

and surveillance
HIV surveillance
not that

b. Research on Effective Prevention Strategies

Effective interventions must be based on sound research findings and evaluations. Funding for prevention and behavioral research did not receive the same priority in the early years of the epidemic as biomedical research. NIH and CDC are both committed to increasing future support for basic research on behavior, interventions, and social marketing.

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

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

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

[QUESTION: Do we have a program, a budget, an initiative that actually point to action in any of the three research areas?]

c. Strengthening Community-based Programs

Community prevention planning is one of the key innovations in CDC's prevention programming over the

last several years. This public/private partnership puts federal funds to work based on locally designed priorities. The initiative is at a crucial stage of development, and ensuring its success is the third key element of this strategy's prevention agenda. [How long in existence? Is it expanding? What's the plan for 1997?]

Community planning requires ongoing leadership from CDC and its partners as well as the resources to provide the technical assistance the community planning process needs to flourish. Successful HIV prevention often depends on small, new community based organizations, many serving minority populations. These organizations need assistance not just on how to plan and compete successfully for available resources, but also access to the surveillance, epidemiological and behavioral research discussed above.

[Question: What action -- how much money is being put into TA? Is there a new TA initiative?]

d. Program Integration and Collaboration

The fourth (and final element) of the prevention agenda is improving the integration of HIV prevention into other program areas that reach individuals at risk for HIV. HIV prevention programs cannot stand apart from other, related public health efforts.

Substance Abuse HIV transmission is directly related to substance abuse, both directly through needle sharing behavior and indirectly as sex is traded for drugs or drug use impairs judgment and increases risk taking behaviors. Breaking that linkage will require:

- o Integration of HIV prevention into substance abuse treatment and prevention programs. In August, 1996, at the request of President Clinton, the Public Health Service agencies jointly co-sponsored a national meeting of state and local officials, researchers, and community experts from the fields of HIV and substance abuse to develop an action plan to more effectively integrate HIV and substance abuse prevention efforts. These agencies are committed to implementing this strategy in the year ahead.
- o Enrolling more substance abusers into drug treatment. Substance abuse treatment is a major form of HIV prevention. This Administration will continue to press for increased funding for substance abuse treatment. Further, through outreach and demonstration programs, SAMHSA and CDC will work to enroll more people in treatment

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and to find more successful interventions to accomplish this end.

- o Reducing the availability of illegal drugs. The Office of National Drug Control Policy (ONDCP) is leading the fight on two fronts: reducing demand for drugs through treatment and prevention programs, and reducing the availability of drugs through interdiction.
- o Needle exchange. Providing federal support for needle exchange programs remains one of the top priorities of AIDS Service Organizations and activists. Others oppose federal support for needle exchange, fearing it may encourage or legitimize illegal drug use. There is ongoing research and discussion surrounding the issue, and no national political consensus in favor of changing federal policy. Congress has set the parameters for federal funding, and that policy will not be changed without further national dialogue and consensus building.

Primary Care HIV prevention also needs to be better integrated into primary care. New and promising medical interventions make it critical to invest in HIV counseling and testing -- creating a critical bridge between prevention and primary care. CDC is committed to improving the return rate of those tested at publicly funded sites and the quality of referral to services for those who test positive. But the linkage must also go in the opposite direction: from primary care to prevention.

Primary care providers must learn to incorporate a person's sexual and drug using history when a medical history is taken, offering HIV-related counseling and voluntary testing, and providing prevention education to HIV positive individuals as part of the provider-patient relationship. HRSA's AIDS Education and Training Centers (AETCs) have played a crucial role in giving providers the information and skills they need. The Administration is committed to restoring Congressionally-imposed cuts in the AETC program and giving it a renewed focus to support this goal.

Often primary care is a direct form of HIV prevention. The tremendous medical breakthrough that allows the chance of perinatal transmission to be reduced by two-thirds through the use of AZT requires a commitment to assuring that all pregnant women are counseled and offered HIV testing -- and that AZT treatment is available for all who desire it. All federally funded programs reaching pregnant women -- from Medicaid to

Ryan White CARE Act grantees to community and migrant health centers -- are required to take part in this effort. We are committed to expanding outreach and assuring appropriate care so that the Congressionally set goal of reducing perinatal transmission by 50 percent by the year (????) is achieved.

Other STDs and TB Recent research has confirmed that treatment of sexually transmitted diseases (STDs) other than HIV can reduce the likelihood of HIV transmission -- making the need for collaboration between HIV and STD prevention efforts more compelling. Similarly, people living with HIV are at very high risk for developing active tuberculosis. Studies suggest that the risk of developing active TB is 7 to 10 percent per year for persons who are infected with both TB and HIV, as opposed to a 10 percent lifetime risk for persons not infected with HIV. [Question: what is this? a footnote? Personal communication from CDC Division TB Elimination.] [Question: these are statements of fact: links are there, collaboration important -- what are we doing?]

Reviewed by
Lyle Pina h. m.s.f.

person with active TB.

The newly organized National Center for HIV, STD, and TB Prevention at CDC demonstrates the importance of integrating the interdependent aspects of these epidemics. CDC has initiated -- and will aggressively pursue -- efforts to increase collaboration among these programs, including expanding the community planning experiment to cover STD programs.

e. Special Populations

The youth, women, and minorities

There are certain populations where the HIV epidemic has had a disproportionate impact or where HIV infection rates are rising at a worrisome pace. These include youth (especially young gay men), women, and minorities (especially gay men of color), prisoners, and, as discussed above, substance abusers. While many federally funded HIV prevention activities already target these populations, as part of the President's increased funding request for CDC, \$35 million in new funds will be provided for research programs targeting youth, women, and substance abusers.

f. Evaluation

To ensure that prevention programs are actually working -- and so scarce resources are spent on the most effective interventions -- all federally funded prevention activities will routinely include evaluation components. The funding agencies will share widely the knowledge gained about what works and what does not to ensure promotion of best practices in the field. In addition, as part of the federal government's compliance with the Government Performance and Results Act, CDC and SAMHSA will continue to work with its constituents to develop appropriate performance measures for HIV prevention programs.

1. Personal communication from CDC Division TB Elimination.

more to research

T

EXECUTIVE OFFICE OF THE PRESIDENT

15-Aug-1996 05:32pm

TO: Jeffrey Levi

FROM: Jeremy D. Benami
Domestic Policy Council

SUBJECT: research rewrite

opportunities for progress section lists four challenges - then addresses two of them?? Am I missing the last two sections??

B. RESEARCH

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

President Clinton, December 5, 1995, to the White House Conference on HIV and AIDS

1. Record of Accomplishment

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

- o Identification of HIV as the etiologic agent for AIDS,
- o Development of a reliable test to determine exposure to HIV,
- o Approval of zidovudine (AZT), the first treatment of HIV primary infection,
- o Development by the Food and Drug Administration of a system of expedited review of treatments for life-threatening diseases, including HIV.

[Don't protease inhibitors, other drugs belong here??]

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"Don't protease inhibitors, other drugs belong here??"
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Since he took office in 1993, President Clinton has escalated our AIDS research efforts by:

- o Increasing AIDS research funding by 34 percent,
- o Signing the NIH Revitalization Act of 1993, creating a permanent Office of AIDS Research at NIH and vesting it with new authority to plan and implement an annual AIDS research plan,
- o Accelerating AIDS drug approval to record times -- since 1993, the Food and Drug Administration has approved 12 new AIDS drugs and three new diagnostic tests,
- o Supporting research that led to finding that use of AZT during pregnancy, childbirth, and the first six weeks of life can reduce the transmission of HIV from mother to child by two-thirds,
- o Launching a four-year, \$100 million research effort to develop effective topical microbicides;
- o Facilitating creation of the Forum for Collaborative HIV Research to identify opportunities for clinical effectiveness research to improve care for HIV-positive individuals.

Oscar's Contribution to the effort

Contributions of AIDS Research

[Structural question: some of the accomplishments written about below appear in the bullets above, some do not; what's the difference between the bullets and this section. They should probably be combined as far as I can tell. What do you think?]

See below,
if also thinks
that should be
shorter)

AIDS research has had significant benefits beyond the epidemic, in work on many other diseases. AIDS research has, for example, accelerated study of the human immune system, helping to better understand and treat diseases such as cancer; autoimmune diseases, including systemic lupus erythematosus; type I diabetes mellitus; rheumatoid arthritis; and multiple sclerosis. AIDS research also contributes to the prevention of other infectious diseases and provides a new paradigm for treatment of viral diseases.

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

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

Efforts to develop drugs for the treatment of HIV have accelerated the development of methods of rational drug design using sophisticated techniques of structural biology and advanced computer imaging methods. These advances have implications for drug design for virtually all disorders. Comparative clinical trials of poxvirus vectors and vaccine adjuvants in HIV vaccine candidates have supported safety information

for cancer vaccines. Research on HIV-related wasting has provided important information for research on nutritional disorders, metabolic abnormalities, and gastrointestinal dysfunctions.

Due in great part to federally-sponsored AIDS research, a number of new and exciting research advances have brought optimism and opened new areas for investigation. One recent advance has been the development of a new class of drugs known as protease inhibitors. When used in combination with other types of anti-retroviral drugs, there is the potential to dramatically reduce the amount of HIV in the bloodstream, possibly improve a person's clinical status and reduce the risk of HIV transmission.

Another landmark advance in HIV prevention was the demonstration that AZT can dramatically reduce the risk of transmission of HIV infection from a pregnant woman to her child. Advances in effective treatments for HIV-related conditions can prolong and improve the quality of life of persons living with HIV. Breakthroughs in our understanding of the genes and proteins of the human immunodeficiency virus have allowed the development of increasingly effective anti-retroviral drugs.

In addition, the Food and Drug Administration through its expedited review and accelerated approval programs is now approving drugs more rapidly than ever before. Recent planning efforts on the part of various federal Agencies, such as the annual NIH plan for HIV-related research and the Federal Biomedical and Behavioral Research Plan for HIV and AIDS have greatly improved the coordination of HIV research.

2. Future Opportunities for Progress

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

- o Provide leadership and coordination for the federal research effort
- o Develop biomedical interventions that prevent ~~on~~ HIV infection, both a vaccine and a microbicide
- o Develop new and more effective therapies for HIV and related conditions

If we keep
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diseases - then these
can be deleted

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summary

- o Assure adequate funding for this research effort.

a. Leadership and coordination of research.

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

The strengthened authority and new leadership of the NIH Office of AIDS Research and the first Federal Biomedical and Behavioral Research Plan and Budget for HIV and AIDS form the basis for better coordination of our research effort and provide the assurance that key questions are being answered systematically and without duplication. Over the next year, the Administration is committed to reauthorizing the OAR's authority and assuring that its budget powers are maintained throughout the appropriations process.

As part of the ongoing commitment to assess all aspects of our research effort, the OAR convened a panel of outside experts to evaluate the NIH AIDS programs. The report of the insert formal name of Levine committee...included several key recommendations that will be implemented in the year ahead. These include:

[Jane--we should ask NIH for the specifics--but my guess is they are:]

--increase the pool of funds available for investigator-initiated research, so we can expand on the basic science base for drug and vaccine development.

--provide an improved coordination mechanism for all the clinical trials groups funded by the various NIH institutes.

--give new and stronger leadership to the vaccine development programs.

--increase the commitment to behavioral research (can this go here...even though it's sort of prevention???)

[Question: are we committed to implementing the recommendations? What's our position on them?] — 6/1/84

b. Biomedical (is this the right term?) Prevention of HIV infection

Vaccine Development The scientific community remains confident that, ultimately, an effective vaccine against HIV infection can be developed. This is our ultimate goal in the area of prevention and in FY 1997, the NIH plans to increase its commitment to vaccine research by \$xx million.

The federal government, through the NIH and the Department of Defense, will continue to support two approaches to vaccine development. The first approach is based on the belief that gathering additional basic science information offers the best hope in steering vaccine development and that many critical questions must be answered before human trials should begin. The second approach is guided by the belief that data gathered from clinical efficacy trials in humans can lead to the development of a successful candidate and that if a safe candidate is available, it is not necessary to resolve all of the scientific questions before proceeding with human trials. Both approaches will be pursued on a parallel and interrelated path.

Microbicides Many scientists believe that in the absence of a vaccine the development of safe and effective mechanical or chemical barrier methods that will block HIV transmission or prevent other sexually transmitted infections could dramatically reduce the sexual transmission of HIV. Worldwide over 80 percent of HIV infections are acquired heterosexually and women are more easily infected than men. Moreover, the risk of becoming infected or infecting others is substantially increased by the presence of other STDs Alan B. Stone, and Penelope J. Hitchcock. *Vaginal Microbicides for Preventing the Transmission of HIV. AIDS 1994, 8 (suppl 1):S285-S293.*

pursued on a parallel and interrelated path.

Microbicides

Many scientists believe that in the absence of a vaccine the development of safe and effective mechanical or chemical barrier methods that will block HIV transmission or prevent other sexually transmitted infections could dramatically reduce the sexual transmission of HIV. Worldwide, over 80 percent of HIV infections are acquired heterosexually and women are more easily infected than men. Moreover, the risk of becoming infected or infecting others is substantially increased by the presence of other STDs¹.

Condoms, the barrier methods ^{the} that are currently available, have limitations. Most require consent, if not the active participation of both partners and therefore cannot be independently used at the discretion of one partner. An easily available and inexpensive microbicide could provide a prevention option for millions of people worldwide.

To address this goal, the following steps will be taken:

--During FY 1997, the NIH and CDC will begin to implement the four-year, \$100 million initiative on microbicides announced by Secretary of Health and Human Services Donna Shalala at the ~~Twelfth~~ (?) International AIDS Conference.

--The Vice President will continue a high-level dialogue designed to encourage private sector involvement in the development of microbicides.

--Through US participation in UNAIDS, and in other forums, we will encourage international efforts to develop effective microbicides.

c. Developing New and More Effective Therapies.

Developing new and more effective therapies for HIV infection and its associated conditions is a critical priority if we hope to transform HIV disease into a chronic, manageable condition. While the FDA is approving new treatments in record numbers and at record speed, the long-term clinical effectiveness of these new therapies remains unknown. There is no doubt that new drugs must be developed.

To accomplish this end, the Federal government's support for drug development and clinical trials through the NIH will increase by \$xx million in FY 1997. In addition, several other initiatives will be undertaken or maintained:

--Through its support of the Forum for Collaborative HIV Research, the Federal government will promote public-private collaboration in AIDS research. This newly formed group, begun

at the behest of Vice President Gore, is designed to catalyze clinical effectiveness trials of anti-HIV treatments through collaborations between the government research establishment, pharmaceutical companies, and third party payers. The Federal government is committed to being an equal partner in this new effort as it begins its work later this year. (Jane--this could use a slightly better description from the press release of 2 weeks ago)

--The government will continue to provide access to sophisticated equipment and personnel that can be shared among many researchers in both the private and public sectors. The Department of Energy (DOE) has made available the use of sophisticated imaging equipment that would be prohibitively expensive for individual researchers or companies to purchase. This shared resource has accelerated our understanding of molecular structures in a number of research fields, including HIV research. Information gained from this research can form the basis for targeted drug design and development.

--Our research effort will increase its focus on the needs of adolescents, who have not received the full benefit of all research discoveries. Evidence indicates that HIV may behave differently in infected adolescents. We need more information on impact of puberty on the course of HIV infection and behavioral trends that play a key factor in HIV treatment and prevention. Adolescents also must factor more significantly into the research process. NIH and the Food and Drug Administration (FDA) are examining options for lowering barriers to participation of adolescent in clinical trials and research protocols and will continue to encourage sponsors to enroll adolescents when feasible and appropriate, in such trials. The efforts of the collaboratively-funded Adolescent Medicine HIV/AIDS Research Network (Footnote D) are important in improving our understanding of HIV disease in adolescents and will continue.

d. Continued Support for Research.

Research is an investment in our future. It must receive consistent and adequate funding if we hope to bring the best and the brightest to meet the research challenges that will lead to a cure, better therapies, and a vaccine. At present, NIH receives many more outstanding research applications than it is able to fund; these unfunded proposals represent a lost opportunity for scientific progress. Other Departments and Agencies, such as DOD and VA, also support crucially important research that strengthens the overall U.S. research effort. Research has been key to prolonging and improving the quality of lives and the Nation must continue to make this investment. Recognizing the centrality of biomedical research overall and AIDS research generally, the President has requested an increase of \$xxx million for the NIH overall, an increase of \$xx million for NIH-supported AIDS research, and an increase of \$xx million for AIDS

research government-wide.

1. Alan B. Stone, and Penelope J. Hitchcock. Vaginal Microbicides for Preventing the Transmission of HIV. AIDS 1994, 8 (suppl 1):S285-S293.

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

15-Aug-1996 09:14pm

TO: Ursula Sanville
FROM: Jeffrey Levi
 AIDS Policy Council

SUBJECT: research JBA version

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

15-Aug-1996 05:19pm

TO: Jeffrey Levi

FROM: Jeremy D. Benami
 Domestic Policy Council

SUBJECT: research rewrite

opportunities for progress section lists four challenges - then addresses two of them?? Am I missing the last two sections??

B. RESEARCH

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

President Clinton, December 5, 1995, to the White House Conference on HIV and AIDS

1. Record of Accomplishment

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

- o Identification of HIV as the etiologic agent for AIDS,
- o Development of a reliable test to determine exposure to HIV,
- o Approval of zidovudine (AZT), the first treatment of HIV primary infection,
- o Development by the Food and Drug Administration of a system of expedited review of treatments for life-threatening diseases, including HIV.

[Don't protease inhibitors, other drugs belong here??]

Since he took office in 1993, President Clinton has escalated our AIDS research efforts by:

*we risk
looking
stupid
if
we take
credit*

- W.B. 1993*
not the issue
- o Increasing AIDS research funding by 34 percent,
 - o Signing the NIH Revitalization Act of 1993, creating a permanent Office of AIDS Research at NIH and vesting it with new authority to plan and implement an annual AIDS research plan,
 - o Accelerating AIDS drug approval to record times -- since 1993, the Food and Drug Administration has approved 12 new AIDS drugs and three new diagnostic tests,
 - o Supporting research that led to finding that use of AZT during pregnancy, childbirth, and the first six weeks of life can reduce the transmission of HIV from mother to child by two-thirds,
 - o Launching a four-year, \$100 million research effort to develop effective topical microbicides;
 - o Facilitating creation of the Forum for Collaborative HIV

Research to identify opportunities for clinical effectiveness
research to improve care for HIV-positive individuals.

Contributions of AIDS Research

[Structural question: some of the accomplishments written about below appear in the bullets above, some do not; what's the difference between the bullets and this section. They should probably be combined as far as I can tell. What do you think?]

AIDS research has ^{provided} had significant benefits beyond the epidemic, in work on many other diseases. AIDS research has, ~~for example,~~ accelerated study of the human immune system, helping to better understand and treat diseases such as cancer; autoimmune diseases, including systemic lupus erythematosus; type I diabetes mellitus; rheumatoid arthritis; and multiple sclerosis. AIDS research also contributes to the prevention of other infectious diseases and provides a new paradigm for treatment of viral diseases.

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

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

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

abnormalities, and gastrointestinal dysfunctions.

Advances in AIDS.
new classes

Due in great part to federally-sponsored AIDS research, a number of new and exciting research advances have brought optimism and opened new areas for investigation. One recent advance has been the development of a new class of drugs known as protease inhibitors. When used in combination with other types of anti-retroviral drugs, there is the potential to dramatically reduce the amount of HIV in the bloodstream, possibly improve a person's clinical status and reduce the risk of HIV transmission.

076

Another landmark advance in HIV prevention was the demonstration that AZT can dramatically reduce the risk of transmission of HIV infection from a pregnant woman to her child. Advances in effective treatments for HIV-related conditions can prolong and improve the quality of life of persons living with HIV. Breakthroughs in our understanding of the genes and proteins of the human immunodeficiency virus have allowed the development of increasingly effective anti-retroviral drugs.

Accelerated Approval.

In addition, the Food and Drug Administration through its expedited review and accelerated approval programs is now approving drugs more rapidly than ever before. Recent planning efforts on the part of various federal Agencies, such as the annual NIH plan for HIV-related research and the Federal Biomedical and Behavioral Research Plan for HIV and AIDS have greatly improved the coordination of HIV research.

2. Future Opportunities for Progress

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

- o Provide leadership and coordination for the federal research effort
- o Develop biomedical interventions that prevent HIV infection, [both a vaccine and a microbicide]
- o Develop new and more effective therapies for HIV and related conditions
- o Assure adequate funding for this research effort.

a. Leadership and coordination of research.

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

Topic Sentence
The strengthened authority and new leadership of the NIH Office of AIDS Research and the first Federal Biomedical and Behavioral Research Plan and Budget for HIV and AIDS form the basis for better coordination of our research effort and provide the assurance that key questions are being answered systematically and without duplication. Over the next year, the Administration is committed to reauthorizing the OAR's authority and assuring that its budget powers are maintained throughout the appropriations process.

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

deserve careful consideration

[Jane--we should ask NIH for the specifics--but my guess is they are:]

--increase the pool of funds available for investigator-initiated research, so we can expand on the basic science base for drug and vaccine development. *Increase basic science by increasing*

Increase commitment to
--provide an improved coordination mechanism for all the clinical trials groups funded by the various NIH institutes.

--give new and stronger leadership to the vaccine development programs.

--increase the commitment to behavioral research (can this go here...even though it's sort of prevention???) *yes call it Develop a comprehensive NIH HIV Prevention Science Agenda*

[Question: are we committed to implementing the recommendations? What's our position on them?] *No*

b. Biomedical (is this the right term?) Prevention of HIV infection

Vaccine Development The scientific community remains confident that, ultimately, an effective vaccine against HIV infection can be developed. This is our ultimate goal in the area of

prevention and in FY 1997, the NIH plans to increase its commitment to vaccine research by \$xx million.

The federal government, through the NIH and the Department of Defense, will continue to support two approaches to vaccine development. The first approach is based on the belief that gathering additional basic science information offers the best hope in steering vaccine development and that many critical questions must be answered before human trials should begin. The second approach is guided by the belief that data gathered from clinical efficacy trials in humans can lead to the development of a successful candidate and that if a safe candidate is available, it is not necessary to resolve all of the scientific questions before proceeding with human trials. Both approaches will be pursued on a parallel and interrelated path.

Microbicides Many scientists believe that in the absence of a vaccine the development of safe and effective mechanical or chemical barrier methods that will block HIV transmission or prevent other sexually transmitted infections could dramatically reduce the sexual transmission of HIV. Worldwide over 80 percent of HIV infections are acquired heterosexually and women are more easily infected than men. Moreover, the risk of becoming infected or infecting others is substantially increased by the presence of other STDs Alan B. Stone, and Penelope J. Hitchcock. Vaginal Microbicides for Preventing the Transmission of HIV. AIDS 1994, 8 (suppl 1):S285-S293.

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

14-Aug-1996 11:48pm

TO: Jeremy D. Benami
FROM: Jeffrey Levi
 AIDS Policy Council
CC: Ursula Sanville
SUBJECT: Research--revised version

Jeremy--another section...again, not formatted perfectly, and with few factual gaps -- but I hope more in line with an active approach--Jeff

B. RESEARCH

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

President Clinton, December 5, 1995, to
the White House Conference on HIV and AIDS

1. Record of Accomplishment

Since the epidemic began in 1981, the Nation has made significant advances in HIV-related research advances. Sentinel points of that progress include:

- ? Identification of HIV as the etiologic agent for AIDS (April 1984);
- ? Development of a reliable test to determine exposure to HIV (March 1985);
- ? Approval of zidovudine (AZT), the first treatment of HIV primary infection (September 1986); and
- ? Development by the Food and Drug Administration of a system of expedited review of treatments for life-threatening diseases, including HIV.

Since he took office in 1993, President Clinton has escalated our AIDS research efforts by:

- ? Increasing AIDS research funding by 34 percent;
- ? Signing the NIH Revitalization Act of 1993, creating a

permanent Office of AIDS Research at NIH and vesting it with new authority to plan and implement an annual AIDS research plan;

- ? Accelerating AIDS drug approval to record times. (Since 1993, the Food and Drug Administration has approved 12 new AIDS drugs and three new diagnostic tests.)
- ? Supporting research that led to finding that use of AZT during pregnancy, childbirth, and the first six weeks of life can reduce the transmission of HIV from mother to child by two-thirds;

- ? Launching a four-year, \$100 million research effort to develop effective topical microbicides;
- ? Facilitating creation of the Forum for Collaborative HIV Research to identify opportunities for clinical effectiveness research to improve care for HIV-positive individuals.

Contributions of AIDS Research

Beyond the impact that AIDS research has had on the epidemic, the Nation has realized additional benefits of supporting such research. Several Federal Agencies play a significant role in AIDS research (see Appendix B). The effort to understand HIV and AIDS has produced scientific advances that benefit research on many other diseases. For example, AIDS research has accelerated study of the human immune system, which helps us to better understand and treat many other diseases, such as cancer; autoimmune diseases, including systemic lupus erythematosus; type I diabetes mellitus; rheumatoid arthritis; and multiple sclerosis. AIDS research also contributes to the prevention of other infectious diseases and provides a new paradigm for treatment of viral diseases.

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

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

Efforts to develop drugs for the treatment of HIV have accelerated the development of methods of rational drug design using sophisticated techniques of structural biology and advanced computer imaging methods. These advances have implications for

drug design for virtually all disorders. Comparative clinical trials of poxvirus vectors and vaccine adjuvants in HIV vaccine candidates have supported safety information for cancer vaccines. Research on HIV-related wasting has provided important information for research on nutritional disorders, metabolic abnormalities, and gastrointestinal dysfunctions.

Due in great part to Federally-sponsored AIDS research, a number of new and exciting research advances have brought optimism and opened new areas for investigation. One of the recent research advances has been the development of a new class of drugs, known as protease inhibitors. When used in combination with other types of anti-retroviral drugs, there is the potential to dramatically reduce the amount of HIV in the bloodstream and possibly improve a person's clinical status and reduce the risk of HIV transmission. A landmark advance in HIV prevention was the demonstration that AZT can dramatically reduce the risk of transmission of HIV infection from a pregnant woman to her child. Advances in effective treatments for HIV-related conditions can prolong and improve the quality of life of persons living with HIV. Breakthroughs in our understanding of the genes and proteins of the human immunodeficiency virus have allowed the development of increasingly effective anti-retroviral drugs.

In addition, the Food and Drug Administration through its expedited review and accelerated approval programs is now approving drugs more rapidly than ever before. Recent planning efforts on the part of various Federal Agencies, such as the annual NIH plan for HIV-related research and the Federal Biomedical and Behavioral Research Plan for HIV and AIDS have greatly improved the coordination of HIV research.

2. Future Opportunities for Progress

While tremendous progress has been made in biomedical research, we cannot and will not diminish our effort until we have found a cure and a preventive vaccine. To accomplish this, we must address four ongoing challenges:

- Provide leadership and coordination for the federal research effort.
- Develop biomedical interventions that prevent HIV infection, both a vaccine and a microbicide.
- Develop new and more effective therapies for HIV and related conditions.
- Assure adequate funding for this research effort.

a. Leadership and coordination of research.

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

The strengthened authority and new leadership of the NIH Office of AIDS Research and the first Federal Biomedical and Behavioral Research Plan and Budget for HIV and AIDS form the basis for better coordination of our research effort and provide the assurance that key questions are being answered systematically and without duplication. Over the next year, the Administration is committed to reauthorizing the OAR's authority and assuring that its budget powers are maintained throughout the appropriations process.

As part of the ongoing commitment to assess all aspects of our research effort, the OAR convened a panel of outside experts to evaluate the NIH AIDS programs. The report of the insert formal name of Levine committee...included several key recommendations that will be implemented in the year ahead. These include:

Jane--we should ask NIH for the specifics--but my guess is they are:

--increase the pool of funds available for investigator-initiated research, so we can expand on the basic science base for drug and vaccine development.

--provide an improved coordination mechanism for all the clinical trials groups funded by the various NIH institutes.

--give new and stronger leadership to the vaccine development programs.

--increase the commitment to behavioral research (can this go here...even though it's sort of prevention???)

b. Biomedical (is this the right term?) Prevention of HIV infection.

Vaccine Development.

The scientific community remains confident that ultimately, an effective vaccine against HIV infection can be developed. This

is our ultimate goal in the area of prevention and in FY 1997, the NIH plans to increase its commitment to vaccine research by \$xx million.

The Federal government, through the NIH and the Department of Defense, will continue to support two approaches to vaccine development. The first approach is based on the belief that gathering additional basic science information offers the best hope in steering vaccine development and that many critical questions must be answered before human trials should begin. The second approach is guided by the belief that data gathered from clinical efficacy trials in humans can lead to the development of a successful candidate and that if a safe candidate is available, it is not necessary to resolve all of the scientific questions before proceeding with human trials. Both approaches will be pursued on a parallel and interrelated path.

Microbicides

Many scientists believe that in the absence of a vaccine the development of safe and effective mechanical or chemical barrier methods that will block HIV transmission or prevent other sexually transmitted infections could dramatically reduce the sexual transmission of HIV. Worldwide over 80 percent of HIV infections are acquired heterosexually and women are more easily infected than men. Moreover, the risk of becoming infected or infecting others is substantially increased by the presence of other STDs¹

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

To address this goal, the following steps will be taken:

- During FY 1997, the NIH and CDC will begin to implement the four-year, \$100 million initiative on microbicides announced by Secretary of Health and Human Services Donna Shalala at the Twelfth (?) International AIDS Conference.

- The Vice President will continue a high-level dialogue designed to encourage private sector involvement in the development of microbicides.

- Through US participation in UNAIDS, and in other forums, we

1. Alan B. Stone, and Penelope J. Hitchcock. Vaginal Microbicides for Preventing the Transmission of HIV. AIDS 1994, 8 (suppl 1):S285-S293.

will encourage international efforts to develop effective microbicides.

c. Developing New and More Effective Therapies.

Developing new and more effective therapies for HIV infection and its associated conditions is a critical priority if we hope to transform HIV disease into a chronic, manageable condition. While the FDA is approving new treatments in record numbers and at record speed, the long-term clinical effectiveness of these new therapies remains unknown. There is no doubt that new drugs must be developed.

To accomplish this end, the Federal government's support for drug development and clinical trials through the NIH will increase by \$xx million in FY 1997. In addition, several other initiatives will be undertaken or maintained:

--Through its support of the Forum for Collaborative HIV Research, the Federal government will promote public-private collaboration in AIDS research. This newly formed group, begun at the behest of Vice President Gore, is designed to catalyze clinical effectiveness trials of anti-HIV treatments through collaborations between the government research establishment, pharmaceutical companies, and third party payers. The Federal government is committed to being an equal partner in this new effort as it begins its work later this year. (Jane--this could use a slightly better description from the press release of 2 weeks ago)

--The government will continue to provide access to sophisticated equipment and personnel that can be shared among many researchers in both the private and public sectors. The Department of Energy (DOE) has made available the use of sophisticated imaging equipment that would be prohibitively expensive for individual researchers or companies to purchase. This shared resource has accelerated our understanding of molecular structures in a number of research fields, including HIV research. Information gained from this research can form the basis for targeted drug design and development.

--Our research effort will increase its focus on the needs of adolescents, who have not received the full benefit of all research discoveries. Evidence indicates that HIV may behave differently in infected adolescents. We need more information on impact of puberty on the course of HIV infection and behavioral trends that play a key factor in HIV treatment and prevention. Adolescents also must factor more significantly into the research process. NIH and the Food and Drug Administration (FDA) are examining options for lowering barriers to participation of adolescent in clinical trials and research protocols and will continue to encourage sponsors to enroll adolescents when

feasible and appropriate, in such trials. The efforts of the collaboratively-funded Adolescent Medicine HIV/AIDS Research Network (Footnote D) are important in improving our understanding of HIV disease in adolescents and will continue.

d. Continued Support for Research.

Research is an investment in our future. It must receive consistent and adequate funding if we hope to bring the best and the brightest to meet the research challenges that will lead to a cure, better therapies, and a vaccine. At present, NIH receives many more outstanding research applications than it is able to fund; these unfunded proposals represent a lost opportunity for scientific progress. Other Departments and Agencies, such as DOD and VA, also support crucially important research that strengthens the overall U.S. research effort. Research has been key to prolonging and improving the quality of lives and the Nation must continue to make this investment. Recognizing the centrality of biomedical research overall and AIDS research generally, the President has requested an increase of \$xxx million for the NIH overall, an increase of \$xx million for NIH-supported AIDS research, and an increase of \$xx million for AIDS research government-wide.

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

15-Aug-1996 09:13pm

TO: Ursula Sanville

FROM: Jeffrey Levi
 AIDS Policy Council

SUBJECT: prevention section rewrite by JBA

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

15-Aug-1996 09:12pm

TO: Jeremy D. Benami
FROM: Jeffrey Levi
 AIDS Policy Council
CC: Ursula Sanville
SUBJECT: rest of strategy

Jeremy--here's the rest. Your changes look good -- we'll take care of addressing the questions you had.

In exchange for giving you the missing part of research -- there seem two last sections of prevention missing in your edit -- re special pop and evaluation -- I assume you did not delete them (they are quite imp and special pops is the focus of our budget increase in 97).

Re needles language -- I think this does nothing to appease anyone, so may still provoke our friends.

thanks again for helping with this.

jeff

c. Developing New and More Effective Therapies.

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DRAFT: National AIDS Strategy
August 9, 1996 (n:\text6.g96)

--The government will continue to provide access to sophisticated equipment and personnel that can be shared among many researchers in both the private and public sectors. The Department of Energy (DOE) has made available the use of sophisticated imaging equipment that would be prohibitively expensive for individual researchers or companies to purchase. This shared resource has accelerated our understanding of molecular structures in a number of research fields, including HIV research. Information gained from this research can form the basis for targeted drug design and development.

--Our research effort will increase its focus on the needs of adolescents, who have not received the full benefit of all research discoveries. Evidence indicates that HIV may behave differently in infected adolescents. We need more information on impact of puberty on the course of HIV infection and behavioral trends that play a key factor in HIV treatment and prevention. Adolescents also must factor more significantly into the research process. NIH and the Food and Drug Administration (FDA) are examining options for lowering barriers to participation of adolescent in clinical trials and research protocols and will continue to encourage sponsors to enroll adolescents when feasible and appropriate, in such trials. The efforts of the collaboratively-funded Adolescent Medicine HIV/AIDS Research Network (Footnote D) are important in improving our understanding of HIV disease in adolescents and will continue.

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Research is an investment in our future. It must receive consistent and adequate funding if we hope to bring the best and the brightest to meet the research challenges that will lead to a cure, better therapies, and a vaccine. At present, NIH receives many more outstanding research applications than it is able to fund; these unfunded proposals represent a lost opportunity for scientific progress. Other Departments and Agencies, such as DOD and VA, also support crucially important research that strengthens the overall U.S. research effort. Research has been key to prolonging and improving the quality of lives and the Nation must continue to make this investment. Recognizing the centrality of biomedical research overall and AIDS research generally, the President has requested an increase of \$xxx

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August 9, 1996 (n:\text6.g96)

million for the NIH overall, an increase of \$xx million for NIH-supported AIDS research, and an increase of \$xx million for AIDS research government-wide.

C. CARE & SERVICES

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

President Clinton, May 20, 1996

Signing of the Ryan White CARE Act Reauthorization

1. Record of Accomplishment

Since the epidemic of HIV and AIDS began in 1981, more than 500,000 Americans have been diagnosed with AIDS and required care. As the number of Americans living with AIDS increased, the demands on the U.S. health care system increased dramatically. Federal, State, and local governments along with community-based organizations and private clinicians have responded with compassionate, high-quality medical care. Among the sentinel achievements of these efforts are:

- ? Enactment in 1989 of the Housing Opportunities for People with AIDS (HOPWA) program; and
- ? Enactment in 1990 of the Ryan White Comprehensive AIDS Resources Emergency (CARE) Act.

The Nation has made significant efforts to ensure that people living with HIV have access to services that are affordable, of high quality, and responsive to their needs. As the number of people with HIV has increased, so did their need for care. In 1985, Federal expenditures for HIV-related care and services were \$xxx, by 1995 the Federal share reached \$xxx.

Since he took office in 1993, President Clinton has, as one of his highest priorities, sought to increase the national commitment to care for people living with HIV or AIDS. Among those actions are:

- ? Signing the Ryan White CARE Act Amendments of 1996, and increasing funding for the Ryan White CARE Act by 134 percent;
- ? More than doubling funding for the AIDS Drug Assistance Program, which helps uninsured and underinsured individuals purchase prescription drugs;
- ? Increasing funding for Housing Opportunities for People with AIDS by 96 percent;
- ? Fighting to preserve the Medicaid guarantee of coverage for the over 50 percent of people with AIDS and 92 percent of children with AIDS who rely on this program for their health coverage; and
- ? Revising eligibility rules for Social Security disability benefits to make it easier for people living with HIV to qualify for benefits.

Background

In the early years of the epidemic, the health care infrastructure was particularly unprepared to accommodate the health care needs of persons with HIV. To meet their complex health care needs, HIV-positive persons were often forced to negotiate a fragmented system of care. There were few programs designed to meet the unique care needs of positive individuals. Moreover, available care services were often directed towards meeting the acute care needs of persons diagnosed with AIDS, rather than the early stages of HIV disease. While we still have far to go, the quality and availability of services for HIV-positive persons has improved significantly.

People living with HIV now access and finance necessary health care services in a variety of ways. Currently, over 50 percent of adult Americans and 90 percent of children living with AIDS receive their medical coverage through the Medicaid program and another 5 percent receive Medicare benefits. An estimated 15 percent of people living with AIDS have private health insurance and the remaining 30 percent are uninsured and must rely on

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personal payment or charity care.1

[Note to JBA: I think the next two paragraphs could be deleted -- what do you think? It flows better without them, though this denies us a chance to restate some of the Medicaid case.]

For those who qualify, care and services are also provided through a number of Federal Agencies (See Appendix C), many in cooperation with local organizations and the AIDS community, that have admirably served those living with HIV. Taken together, these efforts form a valuable, if still incomplete, safety net for some of the most vulnerable people in our Nation.

Medicaid, a jointly financed Federal-State program of health care for the poor and the disabled, is the primary source of care for people living with AIDS and a major source of care for those who are living with HIV. In FY 1996, Federal Medicaid expenditures for people living with AIDS totaled \$1.8 billion. The Medicaid statute authorizes Federal matching payments to the states to provide services to eligible individuals.

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

? Titles I and II of the CARE Act provide funds for outpatient care, support services, and case management that are given to cities and States primarily on a formula basis. Title II also provides drug reimbursement funding for persons living with HIV/AIDS under the AIDS Drug Assistance Program (ADAP).

? Title IIIb of the CARE Act provides early intervention services such as counseling and testing, medical care, and educational services for medically underserved persons with the goal of reducing HIV-related illness.

1. JL cite. Add Vancouver numbers.

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? Title IV seeks to increase the availability of research and care and services for women, infants, children, and youth in a community-based family-centered system of care.

HRSA also provides primary care to persons living with HIV through its Community Health Centers and Maternal and Child Health Programs. Other sources of primary care supported by the Federal government include the Department of Defense, the Department of Veterans Affairs, and the Indian Health Service (IHS), which provides health care for HIV-positive Native Americans and Alaska Natives. Additionally, the Bureau of Prisons within the Department of Justice provides care for HIV-positive people in Federal prisons.

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

To further foster community involvement, HUD also has established the Consolidated Planning process for communities that receive funds under the Department's economic and community development programs, including recipients of HOPWA formula allocations. The Community Development Block Grant (CDBG), the HOME affordable housing program, as well as public housing programs are key resources that are available to communities.

2. Future Opportunities for Progress

The challenge before us today is to ensure that persons living with HIV receive the care they need so they may have the opportunity to live productive lives. AIDS care and service programs must continue to expand access to care for those without insurance coverage, improve prioritization and accountability, and increase the cost-effectiveness of services they provide. As treatments improve and extend the productive lives of people with HIV, we must continually reexamine the range of services that are needed.

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The Administration's efforts will focus in two areas:

- o Maintaining HIV-related care and services as an investment priority in budgeting, which translates into fighting to preserve Medicaid and continuing to seek increases in funding for CARE Act and HOPWA programs.
- o Policy initiatives that assure resources are used as effectively as possible.

Preserving Medicaid. Medicaid is a lifeline of support for Americans living with HIV and AIDS. As the epidemic continues to spread in lower-income communities, the need for Medicaid coverage of people living with HIV/AIDS will increase. The need to maintain the historic Federal-State partnership on Medicaid has never been greater. Proposals in Congress to convert Medicaid into a block grant would endanger access to care for people living with HIV/AIDS. In particular, proposals to eliminate the Federal guarantee of coverage for people living with disabilities would have a dramatic impact on people living with HIV/AIDS. President Clinton has vetoed one such proposal and has promised to veto any future proposals that reach his desk.

Continuing Support for Ryan White CARE Act. The five-year reauthorization of the CARE Act signed by President Clinton on May 20, 1996 provides people living with HIV/AIDS with peace of mind that support from the Federal government will be there through FY 2000. As the demand for care continues to grow so must the resources for the CARE Act. President Clinton has proposed \$827.5 million for this program in FY 1997; enactment of that request is essential.

Expanding Support for Housing Services. Without stable housing a person living with HIV has diminished access to care and services and a diminished opportunity to live a productive life. It is estimated that up to 50 percent of people living with HIV and AIDS are or will become homeless during the course of their illness.²

2. Housing and the HIV/AIDS Epidemic: Recommendations for Action. National Commission on AIDS. Washington, D.C. July 1992.

DRAFT: National AIDS Strategy
August 9, 1996 (n:\text6.g96)

President Clinton has requested \$196 million in FY 1997 for HOPWA; it is imperative that Congress approve that request.

Providing consistent funding for the housing component of the safety net will continue to be a Federal priority. Integrating AIDS housing services into other programs and ensuring a shared responsibility among Federal, State, local governments and community organizations is another important step in assisting communities to build seamless systems of support for our most vulnerable citizens.

[Note to JBA: I now think this paragraph should probably go -- what it really should be saying is that we want to encourage more people to be tested in programs that improve their quality and link people to care. The problem is -- the community will be scared of this and we can't point to any efforts by the relevant agencies to do so -- they are finally agreeing to a dialogue reassessing the role of counseling and testing, but that is too tentative to include here, I think.

Integrating the Continuum of Care. One of the most effective approaches to treating people living with HIV is providing access to an integrated continuum of health care services. A powerful method of recruiting people into primary care is knowledge of HIV serostatus. People who know their HIV status are more likely to seek health care and act to prevent HIV transmission. Counseling and confidential voluntary testing services serve as a gateway to care. Linking HIV-positive people with care also provides an opportunity for education about behaviors that may reduce their chances of infecting others. CDC and HRSA will be working more closely to assure

Achieving this level of integration requires active collaborative efforts by physicians, nurses, other clinicians, insurance plans, medical schools, and professional organizations in addition to State, local and Federal governments.]

Improving Program Coordination. Organizations receiving funding from the Federal government in providing AIDS-related care often require support from several Federal Agencies. For example, creating a community-based program that integrates primary care, substance abuse treatment and prevention, and sexually transmitted disease screening, HIV prevention, access to clinical trials, and housing assistance requires separate applications to SAMHSA, HRSA, CDC, NIH, and HUD.

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The Agencies funding HIV-related services are committed to simplifying Federal funding applications to facilitate improved integration of service programs. HRSA and SAMHSA have issued joint programs announcements and HUD and HRSA have also issued a joint program announcement for the Special Projects of National Significance (SPNS) program. These efforts to improve integration will be continued and expanded, with special attention given to linking HIV and substance abuse services.

Improving Quality of Care. Federally-supported programs can and should consistently provide high-quality care. Ensuring consistency in care delivery requires increased training for health care professionals and greater accountability through the use of performance measures for quality care. It is also essential that practical information on research advances for practicing clinicians and their patients be provided in a timely manner. (See Section on Translation of Research Advances in Practice.) HRSA and HCFA will continue to offer guidance to grantees and the States regarding maintaining the quality and standard of care appropriate for people living with HIV.

To this end, during FY 1997, the Office of HIV/AIDS Policy at DHHS is undertaking a program to develop clinical practice guidelines in conjunction with other government agencies and private sector clinicians.

Evaluating Program Effectiveness. Strong Federal support for safety net programs must be accompanied by improved accountability and priority setting. Evaluating current activities provides valuable information for planners and those at the front lines of the epidemic and assists them in providing better care to people living with HIV.

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D. CIVIL RIGHTS

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

President Clinton, May 20, 1996

Signing of the Ryan White CARE Act Reauthorization

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

Discrimination also undermines the Nation's efforts to prevent and treat HIV infection and bring the epidemic under control. Because of fear of discrimination and stigma, many people do not voluntarily seek testing for HIV, remain unaware of their HIV status, and consequently do not seek the care that could help them live longer, healthier lives. Opportunities to educate people are also lost as people at-risk avoid prevention programs because of the stigma associated with HIV.

1. Record of Accomplishment

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

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

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accommodation.

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

- ? Vigorously enforcing the ADA by the Justice Department, the Equal Employment Opportunities Commission, and the Department of Health and Human Services. The Federal government has resolved nearly 800 charges alleging discrimination against people with HIV and AIDS obtaining monetary benefits of more than \$6.1 million; [Are these figures correct? .. source(s)?]
- ? Vigorously enforcing Section 504 of the Rehabilitation Act of 1973 as it pertains to recipients of DHHS funds such as hospitals, nursing homes, and social service agencies;
- ? Forcefully opposing the so-called "Dornan Amendment," which would require the discharge of all military personnel who are living with HIV. The President led a successful effort to repeal the "Dornan Amendment" and continues to oppose its enactment;
- ? Establishing an AIDS education program for all Federal workers; [Do we want highlight this?]
- ? Using the Presidential "bully pulpit" to continually speak out against discrimination against people with HIV and AIDS.

2. Future Opportunities for Progress

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

Protecting Workers. The Federal government is actively working to

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

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

Providing Leadership. Leaders of government have an obligation to use the power of their elected office to speak out against acts or words of discrimination against any group of people. President Clinton has used and will continue to use his position to oppose discrimination against people living with HIV/AIDS.

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E. INTERNATIONAL ACTIVITIES

Insert quote:

AIDS is a global epidemic. Eighty percent of new infections occur in developing countries. In the United States it is estimated that between 650,000 and 900,000 people are currently infected with HIV. The World Health Organization (WHO) estimates that 27.9 million adults and over 1.5 million children are currently infected worldwide and there will be 10 to 15 million orphans worldwide attributable to HIV/AIDS by the year 2000. WHO also estimates that two to three million new HIV infections can be expected annually, and by the year 2000, thirty to forty million people will have been infected around the globe.

The epidemic jeopardizes decades of economic and social advances in many developing nations. In the nations of Africa and Asia, economic advances are threatened and in some cases may be reversed due to HIV and AIDS. Socio-economic studies have shown a decrease in overall domestic savings and investment levels, negative effects on foreign investments, reductions in the volumes of imports and exports, and a reduction in receipts from tourism.³

In many countries governments will be forced to cope with increasing numbers of cases, weakened health care systems, a deleterious economic impact on the most productive segments of society, and the reduction in the number of healthy men and women able to serve in the government and the military.

1. Record of Accomplishment

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

- ? Founding of the Global Programme on AIDS in 1987, and
- ? Founding of the United Nations Programme on AIDS (UNAIDS) in 1995 (correct date?).

[NOTE TO JANE: NEED TO HAVE CONSISTENT DEFINITION OF WHAT UNAIDS

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

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STANDS FOR]

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The United States is the largest contributor to international efforts to combat the pandemic of HIV/AIDS. Several Federal Agencies are working to slow the AIDS epidemic internationally. (See Appendix D.) The Department of State works 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 of U.S. leadership in the HIV arena are: preventing new infections; reducing the personal and social impact of the pandemic; and mobilizing and unifying national and international efforts.

The U.S. Agency for International Development (USAID) also plays leadership role in the global HIV effort through development assistance, research and policy formation. USAID focuses its efforts 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 Peace Corps trains a portion of its volunteers to directly address HIV-related concerns in their countries of placement. The U.S. Information Agency (USIA) supports programs that promote dissemination of U.S. policies and information related to HIV and AIDS.

In addition, several Agencies support research overseas, including the National Institutes of Health, the Centers for Disease Control and Prevention, and the Department of Defense. The DOD is conducting clinical trials of candidate HIV vaccines in Thailand and NIH (working in collaboration with USAID) supports 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.

2. Future Opportunities for Progress

International Leadership. The United States has established a global leadership role in combatting the epidemic. This leadership will continue. The U.S. strongly supports the newly established Joint and Co-sponsored United Nations Programme on

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AIDS (UNAIDS).4

The U.S. is a member of the governing body of UNAIDS and signed the 1994 Paris Declaration and the Greater Involvement of People Living with HIV/AIDS Initiative (GIPA).

The U.S. also supports efforts to more effectively access available resources as well as encourage non-traditional donor countries to provide much-needed contributions. Supporting UNAIDS organizations such as UNICEF, WHO, UNDP, the U.S.-Japan Common Agenda and its innovative programmatic efforts, and UNAIDS' goal of working to increase the availability of therapeutics (and vaccines when developed) to the residents of developing countries is not only morally correct, it also furthers U.S. interests by promoting economic and social stability worldwide.

Strengthening Partnerships. In addition to maintaining our multilateral partnerships, we must strengthen and expand our bilateral programs and funds for HIV activities. We must reverse the current trend to reduce assistance to developing countries where more than 90 percent of the world's AIDS cases are found. (OK?)

Sharing Technology and Bringing Lessons Home. Through USAID's "Lessons without Borders Project", the U.S. has gained valuable insights from experiences in participating countries and is applying them to communities here at home. The initiative brings lessons learned abroad back to inner city and rural areas with problems similar to those experienced overseas. These efforts will be continued and should be expanded. [Do we want to say this in light of the USAID cuts, reduced \$ in FY97 PB, etc?]

Improving Program Coordination. One of the most challenging

4. Until recently, the United Nations' response to HIV/AIDS was carried out primarily by the World Health Organization's Global Programme on AIDS. On January 1, 1996 the U.N. launched UNAIDS, co-sponsored by six U.N. agencies to strengthen coordination and focus support for HIV/AIDS activities at the global and country levels. UNAIDS has established three mutually reinforcing roles: to be a major source of policy development and research; provide technical support; and be an advocate for comprehensive, multi-sectoral responses to the pandemic.

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aspects of the U.S. effort is effective coordination among a host

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

F. TRANSLATION OF RESEARCH ADVANCES INTO PRACTICE

Insert Quote

An important element in our fight against AIDS is ensuring that research advances are translated into the care of HIV positive persons. The increasing presence of HIV in every community necessitates that all health care providers become knowledgeable about assessing risk, promoting prevention, and caring for people with HIV.

An example of the importance of such efforts is the translation of the research finding in the NIH-funded study that found that the use of AZT by pregnant women during pregnancy and childbirth and its application to newborns for the first six weeks of life can reduce the risk of perinatal transmission of HIV by two-thirds. Translation of these results required actions by the Centers for Disease Control and Prevention, which prepared guidelines for physicians caring for pregnant women and for consumers; the Health Resources and Services Administration, which provided guidance to grantees on coverage of such services; and the Health Care Financing Administration, which provided similar guidance to State Medicaid Directors and established a demonstration outreach program to encourage Medicaid recipients to take advantage of this breakthrough.

1. Record of Accomplishment

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

- ? The National Institutes of Health (NIH) supports a broad range of efforts including a "Clinical Alerts" mechanism for the dissemination of clinical trials results to health professionals, the media, and the public;
- ? DHHS supports and directs the International HIV/AIDS Clinical Conference Call series, which disseminates critical, state-of-the-art clinical care information to primary care providers via live worldwide audio tele-

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conferencing;

- ? NIH supports publicly available computerized databases such as AIDSDRUGS, AIDSTRIALS, and AIDSLINE;
- ? The toll-free 1-800 TRIALS-A AIDS Clinical Trials Information Service (ACTIS) is co-sponsored by NIH, CDC, and FDA;
- ? The Centers for Disease Control and Prevention disseminates information through the National AIDS Hotline (1-800-342-AIDS); its toll-free 1-800-HIV-0440 HIV/AIDS Treatment Information Service (ATIS); and the AIDS Information Clearinghouse;
- ? The CDC also issues guidelines for health professionals through its Morbidity and Mortality Weekly Report;
- ? The Agency for Health Care Policy and Research (AHCPR) has published a series of HIV-related clinical practice guidelines for clinicians and companion pamphlets for their patients; and,
- ? The Health Resources and Services Administration directs a nationwide system of AIDS Education and Training Centers that provide state of the art HIV clinical information to health care providers. HRSA also has developed guidances for its Ryan White CARE Act grantees and funds an AIDS warmline that responds to questions from clinicians across the country.

2. Future Opportunities for Progress

There are opportunities for improvement in translating research advances into practice. They include:

Increasing Education and Training. As we continue to expand our base of knowledge about AIDS care, efforts to educate and train health care professionals in state-of-the-art care for people living with HIV/AIDS must be expanded. An AHCPR-supported study indicated that primary care physicians may miss significant

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HIV-related symptoms during patient examinations.5
Other research

5. Douglas S. Paauw, Marjorie D. Wenrich, J. Randall
Curtis, Jan D. Carline, Paul G. Ramsey. Ability of
Primary Care Physicians to Recognize Physical Finding
Associated with HIV Infection. JAMA. 1995;
274:1380-1382.

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indicates that a disturbing number of clinicians do not use universal precautions in the course of routine patient care. To reverse this pattern, the Administration is fighting for restoration of funding to the AIDS Education and Training Centers, which play a vital role in training providers.

Disseminating Guidelines. One of the most difficult tasks for clinicians and patients is interpreting the patchwork of data and articles regarding treatments and converting it into a therapeutic strategy for their patients. With every research breakthrough, this task becomes more difficult. It is essential that practical information for practicing clinicians and their patients be provided in a timely manner.

To this end, during FY 1997, the Office of HIV/AIDS Policy at DHHS is undertaking a program to develop clinical practice guidelines in conjunction with other government agencies and private sector clinicians.

Improving Coordination of Federal Activities. Enhancing coordination of information dissemination activities among Public Health Service Agencies is an important priority. Within DHHS, the Office of HIV/AIDS Policy (OHAP) has the lead responsibility for coordinating the HIV-related activities of the Public Health Service Agencies. Ensuring that information about a research breakthrough is easily available, reaches the appropriate people and organizations, and that policies and standard-of-care practices for Federally-sponsored programs are modified to reflect the new standard, requires a continued high level of cooperation and coordination among Public Health Service Agencies.

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

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reaches those who can make a difference.