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AIDS - General [2]

AIDS-general

QUICK REFERENCE AIDS TALKING POINTS

- Discretionary AIDS funding at HHS increased over 60% since 1992
- AIDS research funding at NIH increased by 50% since 1992.
- Specific Federal Funding for State AIDS Drug Assistance Program (ADAP) up nearly 450% since 1996.
- Nearly tripled funding for the Ryan White CARE Act since 1992.
- HIV Prevention funding for the Centers for Disease Control and Prevention up 27% since 1992.

AIDS-general

Todd A. Summers
12/04/97 09:49:33 AM

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cc:
Subject: TALKING POINTS and Q&A FOR PRESIDENT'S ADVISORY COUNCIL MEETING

TALKING POINTS ON REPORT FROM
PRESIDENT'S ADVISORY COUNCIL ON HIV/AIDS

The Clinton Administration continues its aggressive campaign against the AIDS epidemic

- Obtained substantial increases in AIDS funding (discretionary programs at HHS up 60% since start of term)
- Established the HIV Vaccine Initiative, with goal of finding vaccine against HIV within 10 years
- Supported reauthorization and funding of Ryan White CARE Act - funding nearly tripled since start of Administration
- Supported research that resulted in the new treatments that are saving so many lives - funding for AIDS research at NIH increased 50% since start of Administration
- Increased specific Federal funding for the State AIDS Drug Assistance Program nearly 450% since 1996
- Created and Supported the Office of National AIDS Policy
- Protected Medicaid, which serves 50% of people with AIDS and 90% of children with AIDS

Role of the President's Advisory Council is to provide advice from the community

- We understand frustration of Council members - this is a terrible epidemic that gives rise to strong emotions
- If some members choose to resign, we respect but regret their decision - however, it would be our hope that they will stay at the table and work with the President to continue to make a difference
- President and the Secretary will continue to work with the Council to review their reports and to respond quickly and decisively

The appropriateness of needle exchange programs should be determined by public health experts and scientists, not politicians

- Administration worked aggressively to preserve the Secretary's authority to make determination on removing Congressionally imposed restriction on allowing local communities to decide on the use of federal funding for needle exchange programs
- Authority should remain with the Secretary because she is the chief public health officer of this country and with community public health experts -- this is an issue for public health experts to resolve
- Congress agreed, sustaining the Secretary's authority
- Secretary is evaluating available scientific reviews of needle exchange programs to determine appropriate course of action

Q & A
Meeting of and Report from the
President's Advisory Council on HIV/AIDS
December, 1997

The PACHA accuses the Administration of having stalled on the AIDS crisis. Is this true?
No. President Clinton and his Administration remain fully engaged in the effort to end this epidemic. We have supported substantial increases in AIDS funding for care, prevention, and research, even at a time when overall discretionary funding has been tight.

Our accomplishments are remarkable. Investments in AIDS research have resulted in powerful new treatments that have helped reduce the numbers of AIDS deaths for the first time since the start of the epidemic. The Ryan White program, now funded at over a billion dollars, has allowed for a broad array of primary care and supportive services that is unparalleled. We have established a major initiative to find a vaccine against HIV within ten years.

The PACHA is expressing understandable frustration with a devastating epidemic. Presidential advisory councils are not intended to serve as "rubber stamps;" on the contrary, they are intended to provide independent, objective advice to the Administration. No doubt they are using this public document as a means to continue their advocacy with this Administration.

What do you say to the PACHA members who are threatening to resign if the Administration does not approve needle exchange programs?
We certainly understand the frustration of some of members of the President's Advisory Council on HIV/AIDS (PACHA). While their participation in the PACHA process is the most effective way for them to work with the Administration, they certainly have the right to choose to remove themselves. Unfortunately, that means that they will not have a voice at the table.

This Administration is very concerned about the continued spread of this epidemic, and is seriously reviewing the impact of needle exchange programs on curtailing HIV transmission among injection drug abusers. We worked diligently with the Congress to maintain the authority of the Secretary of Health and Human Services to remove the current restriction on the use of federal funds by local communities that choose to implement needle exchange programs. We did this because we believe that this is an issue best left to the public health experts and not to the politicians.

Is the President going to allow funding for needle exchange programs?
The decision to lift the Congressionally imposed restriction on the use of federal funds for needle exchange programs has been vested by Congress with the Secretary of Health and Human Services. She has not yet made that determination because she is studying the benefit of those programs in reducing HIV transmission and their impact on the use of illegal drugs. This is not the simple and obvious decision as has been characterized by AIDS activists. On the contrary, this nation has an epidemic of illegal drug use and we do not want to support something to address AIDS that will undermine our efforts on the drug epidemic. The President will continue to support the Secretary's process, and respects her ability to make a decision on needle exchange that is grounded in science and public health.

The PACHA is debating HIV names reporting? What is that and what is the Administration's position?
Many AIDS advocates, epidemiologists, and government officials now believe that our efforts to fight the AIDS epidemic would be improved with better information on the incidence of HIV infection. We currently rely primarily on the numbers of AIDS diagnoses or deaths as a measure of where this epidemic is currently and where it seems to be moving. However, because more and more people are living longer and longer with HIV and not progressing to AIDS, this data is increasingly out of pace with the front edge of the epidemic. This reduces our ability to initiate the kind of proactive prevention efforts necessary to stem the tide of new infections.

However, we are also very mindful of the very real concerns around confidentiality. The fear of disclosure of a positive HIV test result may inhibit many from getting tested, which is the first step in accessing medical care and avoiding further transmission. The Administration will continue to work with government and community experts to determine the best way to balance the need for more timely information on new infections with the imperative to promote HIV testing and access to care for those infected.

Message Sent To:

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AIDS - general

Presidential Advisory Council on HIV/AIDS
Executive Summaries

Re-Write #3

Preamble
EMBARGOED UNTIL FURTHER NOTICE

In the five years since he assumed office, the President has dramatically improved the national response to AIDS. Since 1993, funding for the Ryan White CARE Act has increased by 200 percent, spending on AIDS research has grown by 50 percent, HIV prevention funding has increased by 27 percent, and federal support for the Housing Opportunities for People With AIDS program has grown by 104 percent. Due in large measure to the Office of AIDS Research, which was created by the Clinton Administration, AIDS research funds are spent more efficiently and strategically, with an enhanced emphasis on basic science. As a result of improvements in medical management of HIV disease, the nation has witnessed the first decline in the annual number of AIDS deaths. In addition, the President's vaccine initiative has placed a long-overdue spotlight on the world's reliance on the U.S. for the development of a safe, effective vaccine. As history will undoubtedly record, President Clinton is the first American chief executive to take the AIDS crisis seriously.

Most of these important strides occurred during the President's first term. Early in his second term, the President, by his appointment of our former PACHA colleague Sandra Thurman as Director of the Office of AIDS policy, raised hopes that even greater progress would be made towards ending this epidemic. This appointment of an experienced community AIDS program administrator who also has the President's ear was applauded by many as a visible sign of renewed commitment to priority status for AIDS issues during the second term. However, despite substantial and diligent efforts on the part of Director Thurman, the ONAP staff and PACHA Executive Director Daniel Montoya, and the AIDS advocacy community, progress in the federal response to AIDS has stalled in recent months, contributing to a sense of drift and diminished priority for AIDS advocacy community, in the President's second term. For example, when the future of funding for the AIDS Drug Assistance Program was at risk earlier this year, AIDS advocates were forced to look to Congress, not the White House, for leadership. In May, the Vice President announced an 30-day expedited Administration review of a proposed Medicaid expansion to cover all indigent HIV-infected individuals, yet many months have since passed with no pilot project yet in place and substantial debate and work yet to be done to determine how such an expansion might be achieved.

In one crucial area of the federal response to AIDS -- the national effort to

prevent HIV transmission -- the Administration, like its predecessors, has failed to develop a coherent plan of action. Funding for HIV prevention remains indefensibly limited, particularly when compared with the monumental American bill for medical expenses and lost productivity stemming from HIV disease. With respect to the scarce funding that does flow each year to state and local health departments to support HIV prevention activities, the Centers for Disease Control and Prevention has incorporated community planning as a primary implementation strategy but has abdicated its oversight responsibility to ensure that States and localities target scarce dollars effectively. Despite the fact that evidence has long existed regarding the efficacy of needle exchange programs, the Secretary of Health and Human Services has yet to make the public health determination legally necessary to allow local communities to use federal funds to support this life-saving intervention. On this issue and others that are politically tough but scientifically sound, the Administration has often failed to exhibit the courage needed to pursue public health strategies that have been shown to save lives.

Recent medical developments have injected a spirit of hope in the battle against the disease. Hope, however, is fragile, and apathy is its enemy. Far too many Americans lack access to effective medications, and far too many patients are failing on the new drugs. Due to gaps in access to basic health care and social services, which make it difficult for many people with HIV to comply with demanding treatment regimens, the nation also faces the alarming risk of widespread HIV drug resistance. Tens of thousands of Americans, as many as one-half of them teenagers or young adults, become infected with HIV each year. Globally, new evidence indicates that the number of people infected with the virus is far larger than originally believed, and growing rapidly, underscoring the overwhelming need to develop a vaccine capable of bringing the worldwide epidemic under control.

Unfortunately, it appears that large segments of some populations affected by the epidemic are not enjoying the benefit of recent therapeutic advances. AIDS continues to affect women in increasing numbers. Blacks, Latinos, and other people of color are now squarely in the path of the virus. HIV-infected individuals in the U.S. are, on average, poorer in 1997 than they were 10 years ago. And as the new therapies extend life for many people with HIV, the HIV infected population grows, placing even greater burdens on already strapped systems of care.

With major challenges still ahead, and countless lives in the balance, now is not the time for complacency. History will judge this society by the choices we make. As a nation, we may either demonstrate the conviction and endurance needed to bring the epidemic to an end, or allow apathy and weariness to sow the seeds of even greater loss of life in the future. The right choice requires bold and courageous leadership. In order to take advantage of the solid achievements of this

Administration during its first term and to tackle still daunting issues regarding AIDS which remain, a renewed dedication to action is essential .

Prevention Subcommittee

More than 16 years after the epidemic was first recognized, the United States sill lacks a coherent, effective national strategy to prevent HIV transmission. Experts estimate more than 40,000 Americans will have become infected with HIV this year alone. Despite a wealth of knowledge regarding the elements of an effective HIV prevention strategy, there is little evidence that the nation has made significant progress in reducing the number of new HIV infections in recent years.

During the early years of the epidemic, former Surgeon General C. Everett Koop and eminent organizations, such as the Institutes of Medicine and previous Presidential commissions, recommended that the country adequately invest in programs to provide frank, explicit, culturally relevant HIV prevention information to those at risk for sexual transmission. Similarly, leading experts have long recommended that the nation's leaders ensure the availability of drug treatment on demand and address drug laws that facilitate the sharing of contaminated needles. Yet, many years later, our nation's prevention efforts ignore these sound recommendations and instead remain timid and undirected.

Studies of the populations most heavily affected by the epidemic have repeatedly demonstrated that prevention initiatives lead to substantial changes in self-reported sexual behavior. This research indicates that prevention programs that address sexual behavior are most effective when they provide explicit information in a clear, culturally sensitive language, are ongoing, assist individuals in developing sexual negotiation skills, and are administered by members of the target population.

Research confirms that it is also possible to reduce the rate of new infections from needle sharing. According to studies, drug treatment programs provide an ideal site for HIV prevention services. Studies of state efforts to reform restrictive needle access laws have correlated such initiatives with marked declines in risk behavior. Likewise, dozens of scientific studies, many of them sponsored by the federal government, have demonstrated that needle exchange programs reduce HIV infection rates without increasing drug use.

While such powerful evidence demands a robust and energetic response, the federal government has responded with meekness. The epidemic's annual price tag in medical care and lost productivity is in the tens of billions of dollars, yet the federal government devotes a mere $___ million toward programs to prevent HIV transmission. When medical costs are included, HIV prevention has declined as a

percentage of government AIDS-related spending.

Worse still, the Administration makes poor use of its limited investment in HIV prevention. The Administration has maintained outdated restrictions on the ability of federally-funded HIV prevention programs to provide explicit information to those at greatest risk, leading HIV prevention educators to censor themselves with an eye to retaining their funding rather than providing the most effective prevention message possible. Moreover, rather than ensure that scarce prevention funds actually go to those in greatest need, the Centers for Disease Control and Prevention inadequately monitors the public health uses to which federal HIV prevention funds are put by state and local health departments. Consequently, one can have little confidence that limited prevention dollars target those at greatest risk and support interventions shown to reduce risk behavior.

Perhaps most dismaying is the continued prohibition on federal funding for needle exchange programs. Fifty percent or more of new HIV infections are traceable to substance use. The Secretary has had the legal authority to lift funding restrictions with a stroke of the pen, yet she has failed to do so. Moreover, the Secretary expended little effort to educate the American public about needle exchange or to build political support for such programs. Although there currently exists a temporary Congressionally-imposed moratorium on exercise of the Secretary's authority to waive funding restrictions and needle exchange, the President should nonetheless show leadership on this issue by immediately certifying the public health utility of this life saving intervention.

Twenty-five percent or more of all new infections occur among individuals under the age of 22. Nonetheless, the CDC's effort to educate youth regarding HIV remains uncoordinated and unevaluated. Rather than address the reality of adolescent sexuality and drug use, our nation's leaders instead too frequently choose denial or hide behind reports that merely chronicle the loss of young lives.

In 1996, President Clinton challenged the nation to reduce the number of new HIV infections each year until there were none. Sadly, no coherent plan exists for achieving this noble objective. In the absence of bold leadership on the part of the Administration, the nation stands little chance of reducing the epidemic's burden in future years.

Research Subcommittee

The President's is to be highly commended for his leadership in efforts to begin the work of developing an AIDS vaccine. The President's announcement of the goal of an AIDS vaccine within a decade in May, 1997, and the focus on an AIDS vaccine during the G-7 meeting is unsurpassed, greatly appreciated and

acknowledged worldwide. But, there is much more that must be accomplished. The Council's recommendations for comprehensive planning and coordination of all Federal efforts, collaboration with the private sector and the international community, the development of an independent AIDS vaccine initiative, a significant and sustained increase in funds from NEW sources and the convening of a public-private AIDS vaccine consultative forum by the Vice-President are still being reviewed and addressed. (ALTERNATIVE: Remaining to be addressed are the Council's prior recommendations for (1) a significant and sustained increase in funding for AIDS vaccine development, (2) a coordinated and comprehensive involvement by all relevant Federal agencies in the effort, (3) close collaboration with the private sector, international community and independent vaccine initiative and (4) the convening under the Vice-President's auspices a public-private AIDS consultative forum.)

The Food and Drug Administration (FDA) is to be commended for its efforts to address some of the issues surrounding gender as recommended by the Council. The Council still needs a follow up report from the FDA on the status of the gender accrual analysis by drug sponsors and the status on dissemination of the guidelines regarding participation of pregnant women in clinical trials. The Council has also been concerned about the lack of data on the effects of HIV therapies in children. We appreciate the FDA's efforts in seeing that labeling of marketed prescriptions drugs includes pediatric data. However, we are still awaiting our requested review of the number of children actually enrolled in NIH-sponsored clinical trials.

The President and Vice-President have continued to support the recommendation for a coordinated Federal approach for HIV/AIDS research through support for the Office of AIDS Research (OAR), including staunch advocacy for a consolidated budget for AIDS research at the NIH. A consolidated budget for OAR is a Congressional responsibility which has not been achieved.

The Council's three recommendations on microbicide research, approved in December 1995, have not yet been fully addressed. No new funds have been allocated for microbicide research, no new full-time equivalents (FTEs) have been designated to this effort, no new Requests for Applications (RFAs) have been issued, nor has a public health consensus panel to assess the efficacy of available spermicides and other licensed products has not been convened.

Our recommendation to create mechanisms for the rapid translation of breakthrough findings into clinical practice has been partially addressed by the NIH in the area of biomedical research. Several approaches now exist. However, in the area of behavioral and social science, creative mechanisms need to be developed that facilitate rapid translation of these research findings. It is the Council's intent to further address this issue in the future.

Services Subcommittee

HIV/AIDS requires extensive medical care. Access to such care beginning as soon as possible after diagnosis is essential and can often result in greatly extending both length and quality of life for those infected. HIV/AIDS medical care is also expensive, and therefore for those without adequate health insurance or significant personal resources often unavailable. The Administration's proposal for universal health insurance would have ensured such care for most HIV-infected Americans. Unfortunately, the Congress rejected that proposal. As a result, we are left with a piecemeal system of health care in which many do not have access to basic primary medical care or the new therapies which offer them the best chance for long term survival. Medicaid, which now covers about 53% of AIDS treatment and the Ryan White CARE Act are the existing programs through which most HIV/AIDS care is currently provided.

Since July, 1996, the Committee has urged the Administration to review existing programs and begin developing new approaches for providing primary medical care and access to these promising new combination drug therapies. A year ago, the Committee heard from HHS that it would develop new treatment guidelines. We advised HHS then, and the President formally in our December, 1996, Council recommendations, to take those steps necessary to ensure that new policies were developed, and funding made available, that would make these life-enhancing, and perhaps life-saving, therapies available to all those who need them, in accordance with those guidelines. In particular, we focused on the following actions:

1) Leadership On Funding for HIV Treatment, Care and Housing Services

The President's budget, which is released each year in early February, is a reflection of the Administration's values and priorities. In 1997, the Council was deeply concerned that the President's FY 98 budget request recommended no increase for the AIDS Drug Assistance Program (ADAP), and only modest increases for primary medical care and other critical support services through the Ryan White CARE Act, and Housing Opportunities for People with AIDS Program (HOPWA). Recent reports of a 23% decline in AIDS deaths between 1995 and 1996 obscures the corresponding 11% increase in the number of people living with AIDS during this same period, many of whom are in need of critical services if they are to benefit from promising new therapies. The Council is looking to the President's FY 9 budget request for a clear indication that the Administration understands both the continuing gravity and urgency of the epidemic and is committed to providing the greatest possible funding support.

2) **Expand Medicaid coverage.** For thousands of people with HIV/AIDS, Medicaid provides their only avenue for primary medical care. Medicaid eligibility is now "triggered" by the on-set of disability, but the new therapies are recommended as a means of *slowing disease progression* and thereby *avoiding* disability. Therefore, the current Medicaid eligibility system is seriously out of alignment with the recommended standard of care for the treatment of HIV disease. Early access to the new therapies with supportive medical and social services is a not only a humane policy, but also, we believe, over the long-term, a cost-effective strategy, based on the possible delay or reduction of expensive hospital and other costs associated with disease progression. Also, many people taking the new therapies are leaving disability income supports and becoming fully employed, tax-paying citizens. Further, unlike the AIDS Drug Assistance Program within the Ryan White CARE Act, which covers only drug costs, Medicaid covers associated primary medical care costs. Moreover, since Medicaid is a needs-based entitlement, rather than subject to special annual appropriations, as is Ryan White, availability of the new drugs and associated medical services is driven by treatment needs, and not by annual appropriations battles.

This past Spring, Vice President Gore called for HHS to explore and report back to him within 30 days the feasibility of expanding Medicaid coverage to cover early intervention HIV therapies. Many dedicated public servants within HHS are working diligently to find a means of expanding Medicaid eligibility, and we commend their efforts. We are particularly encouraged that HCFA has been working closely with the AIDS community and outside policy experts to attempt to develop a viable, cost effective, ethnically appropriate mechanism to provide such expansion. However, we have been deeply disappointed by the apparent absence of personal leadership on this issue from HHS Secretary Shalala. In a recent meeting attended by Council members, the Secretary suggested the possibility of proposing increase support for ADAP. , an option which engenders some skepticism since it was Congress, not the Administration, that proposed increased ADAP spending in the 1998 federal budget, and the Secretary has not committed to making this a top priority either for her or the Administration. Because the quality of life and life itself is at stake for so many thousands of people with HIV/AIDS, we will continue to press hard for Administration leadership

3) **Reduce the cost of the therapies.** The Administration, in conjunction with state AIDS and other public health administrators, and with effective pressure from the advocacy community, have employed, with some success, a number of strategies to bring down the cost of the new combination drug therapies. Also, Vice-President Gore raised the issue in his meetings with the pharmaceutical industry. We believe the Administration is making a sincere and thoughtful effort to try to bring the cost of therapies down, but further efforts is needed to achieve

this goal.

4) Monitor Access to These Therapies and Associated Medical Services in Private Managed Care Health Systems. It has been feared (and in many cases, documented) that people with HIV/AIDS and other complex, disabling conditions would not be able to have access to needed drugs and specialists under managed care systems. The President's Advisory Commission on Consumer Protection and Quality in the Health Care Industry has just released its recommendations, which have been endorsed by the President. These recommendations are sensitive to the special needs and circumstances of people with HIV/AIDS, and are an important first step in assuring that people with HIV/AIDS continue to have access to the new therapies and associated medical services through their managed care providers and/or insurers. We commend Secretaries Herman and Shalala and members of the Commission for this sensitivity and look forward to working with them to ensure implementation of these recommendations. We urge the President to aggressively pursue legislative implementation of the Commission's recommendations.

5) A National Policy Dialogue on How to Provide Comprehensive, Early HIV Care. The Ryan White CARE Act has been a triumph of community and federal responsiveness (on a strongly bipartisan basis), providing critically needed support for a wide range of services for many people with HIV/AIDS, as well as ancillary training, technical assistance, and other support. However, recognizing a shifting in the need for such services for some, the impact of the new drug therapies, and also that many who continue to need Ryan White services are still unserved because of the lack of sufficient appropriations, last December the Council recommended a national dialogue on how, over the long term, the federal government should structure, and pay, for medical and support services for people with HIV/AIDS. Despite significant efforts to promote a formal structured dialogue, progress has stalled and it is not clear how HHS plans to proceed. The changing nature of the epidemic and the need for a comprehensive review of the governmental response demand that such an effort be undertaken at the earliest possible date with active participation of all affected parties.

Discrimination Subcommittee

The Council has formally recommended that mandatory HIV testing by and/or discriminatory policies of the U.S. Foreign Service, the Peace Corps, the Job Corps, the State Department and the military be rescinded unless justified by a compelling

public health rationale. During its meeting with the President two and one-half years ago, the Council raised this issue and the President responded supportively. However, to date, only the Job Corps has revised its policy. It changed from special mandatory testing to routine testing for HIV and now provides requisite counseling and care for those testing HIV positive, regardless of whether they are subsequently accepted as students. This exemplary action by the Job Corps should be commended. The remaining federal agencies targeted by the recommendation have failed to respond in any manner, either to change their policies or to offer any rationale for their continuation. The President should not accept this arrogant evasion of the recommended review of such discriminatory policies.

Additionally, the Center for Disease Control and Prevention has not yet addressed its discredited and discriminatory guidelines concerning HIV-positive health care workers despite clear scientific evidence of their invalidity and repeated promises to the Council that such review would be undertaken.

The moral suasion of the President's vocal condemnation of prejudice-based discrimination is severely undercut by this failure by the federal government to take necessary remedial action regarding its own discriminatory policies.

Prisons Subcommittee

HIV disease has demanded a re-evaluation of the ways in which we have traditionally approached public health. For this reason, the Subcommittee on Prison Issues has examined a number of issues affecting prisoners with HIV and AIDS. Since 1990, HIV and AIDS has been the **second** leading cause of death in prisons. The incidence of AIDS in prisons is six times the incidence in the general population. For many incarcerated persons, prison may be their first contact with medical and psychosocial interventions as well as their first opportunity for alcohol and drug treatment. Therefore, prisons provide an ideal environment for prevention and education efforts. A prisoner's health status **upon returning** to society has a direct bearing on the health of the communities into which they return. A strong investment in HIV prevention and care for incarcerated individuals would be a significant barrier against the spread of HIV.

Information from the Department of Justice concerning health care policy in prisons has been useful; however, the information we have received from the Federal Bureau of Prisons has been incomplete and lacking the substance necessary to reassure us that the well-being of inmates in our nations prisons is not at risk. Information from the Department of Defense concerning military prisons and brigs was also requested, but has not yet been received. A number of concerns outlined in our 1996 report have not yet been addressed. And, many appropriate recommendations from the National Commission on AIDS have not yet been

implemented.

Since most incarcerated individuals do not remain incarcerated forever, discharge planning for inmates with HIV/AIDS is essential. Pre-release case management and discharge planning are important in assuring that HIV-infected inmates who have been released or paroled have access to the broad range of services needed to make a healthy and successful transition back into their communities. We continue to believe that the ABA standards for compassionate release should be reexamined as an alternative to the current Federal Bureau of Prisons guidelines.

During incarceration, inmates must have access to comprehensive and current medical therapy. It is our understanding that Medical Standards of Care include all FDA-approved treatment modalities. Appropriate use of these therapies needs to be closely evaluated. Federal prisoners should have access to compassionate use therapies which are proven efficacious, but not yet FDA-approved. We want to ensure that HIV treatment follows the current Medical Standards of Care recommendations.

The link between HIV and substance abuse has been clearly established, yet access to essential substance use interventions continues to be variable among institutions. Federal officials report that "inmates who volunteer for treatment are admitted into residential substance abuse programs in sequential order based on release date." (10/15/97) While we applaud this effort, we encourage the Federal Bureau of Prisons to evaluate waiting periods and expand programs to accommodate all inmates seeking treatment. In addition, discussions should continue on inmates' access to clean substance use paraphernalia.

Although Federal officials responded to our queries on protective barriers, they remain extremely resistant to changing their current policy which states "condoms and/or dental dams are not medically necessary for use other than during sexual activity and therefore are not authorized." (7/8/97 & 10/15/97). We feel that this approach is short-sighted. Nor are we persuaded by the concern that access to protective barriers would "create an environment in which control would be difficult." (BoP Conference call 10/14/97). The transmission of HIV and other STD's in prison underscores the fact that sexual behavior is indeed occurring; therefore, this policy should be reconsidered and successful models using protective barriers should be examined.

Despite the policies and procedures developed by the Federal Bureau of Prisons, testimony from current and former inmates reveals that these policies are not administered evenly and uniformly. We agree with the Bureau of Prison's claim that "Offenders are incarcerated AS punishment, not FOR punishment." We are concerned that HIV in correctional settings may not be receiving the attention it

deserves. We remain committed to a stronger investment in HIV prevention and care for incarcerated individuals. We believe that this commitment would be a significant barrier against the spread of HIV disease in all of our communities.

International Subcommittee

The global AIDS crisis constitutes a direct threat to the economic and strategic interests of the United States. In light of the ever-worsening global HIV epidemic, the Presidential Advisory Council is disappointed at the apparent failure of the Department of State to conduct an evaluation of the successes and failures of its 1995 "International Strategy on HIV/AIDS". The strategy was developed and issued in 1995 and constituted a two-year plan. It should have been thoroughly assessed, and a current international strategy should have been promptly developed. The global AIDS crisis requires the immediate and consistent attention of the Department of State and the President.

Additionally, insofar as the United States Agency for International Development constitutes the primary U.S. effort to respond to the international AIDS crisis, the Council is similarly concerned that the President has failed to seek increased appropriations for USAID from Congress. The Council emphatically urges the President to request emergency funding for USAID to permit the Agency to immediately increase its global efforts in response to the international explosion of AIDS and HIV. We also strongly urge the President and Secretary of State Albright to consistently and affirmatively reestablish the United States' commitment to lead a global response to the AIDS pandemic.

The Council urges the President to meet with Dr. Peter Piot of UNAIDS at the earliest opportunity to discuss the global AIDS crisis and role of the United States.

AIDS - general

Presidential Advisory Council on HIV/AIDS
~~Executive Summaries~~

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oversight responsibility to ensure that States and localities target scarce dollars effectively. Despite the fact that evidence has long existed regarding the efficacy of needle exchange programs, the Secretary of Health and Human Services has yet to make the public health determination legally necessary to allow local communities to use federal funds to support this life-saving intervention. On this issue and others that are politically tough but scientifically sound, the Administration has often failed to exhibit the courage needed to pursue public health strategies that have been shown to save lives.

Recent medical developments have injected a spirit of hope in the battle against the disease. Hope, however, is fragile, and apathy is its enemy. Far too many Americans lack access to effective medications, and far too many patients are failing on the new drugs. Due to gaps in access to basic health care and social services, which make it difficult for many people with HIV to comply with demanding treatment regimens, the nation also faces the alarming risk of widespread HIV drug resistance. Tens of thousands of Americans, as many as one-half of them teenagers or young adults, become infected with HIV each year. Globally, new evidence indicates that the number of people infected with the virus is far larger than originally believed, and growing rapidly, underscoring the overwhelming need to develop a vaccine capable of bringing the worldwide epidemic under control.

Unfortunately, it appears that large segments of some populations affected by the epidemic are not enjoying the benefit of recent therapeutic advances. AIDS continues to affect women in increasing numbers. Blacks, Latinos, and other people of color are now squarely in the path of the virus. HIV-infected individuals in the U.S. are, on average, poorer in 1997 than they were 10 years ago. And as the new therapies extend life for many people with HIV, the HIV infected population grows, placing even greater burdens on already strapped systems of care.

With major challenges still ahead, and countless lives in the balance, now is not the time for complacency. History will judge this society by the choices we make. As a nation, we may either demonstrate the conviction and endurance needed to bring the epidemic to an end, or allow apathy and weariness to sow the seeds of even greater loss of life in the future. The right choice requires bold and courageous leadership. In order to take advantage of the solid achievements of this Administration during its first term and to tackle still daunting issues regarding AIDS which remain, a renewed dedication to action is essential .

Prevention Subcommittee

More than 16 years after the epidemic was first recognized, the United States sill lacks a coherent, effective national strategy to prevent HIV transmission. Experts estimate more than 40,000 Americans will have become infected with HIV this year alone. Despite a wealth of knowledge regarding the elements of an effective HIV prevention strategy, there is little evidence that the nation has made significant progress in reducing the number of new HIV infections in recent years.

During the early years of the epidemic, former Surgeon General C. Everett Koop and

eminent organizations, such as the Institutes of Medicine and previous Presidential commissions, recommended that the country adequately invest in programs to provide frank, explicit, culturally relevant HIV prevention information to those at risk for sexual transmission. Similarly, leading experts have long recommended that the nation's leaders ensure the availability of drug treatment on demand and address drug laws that facilitate the sharing of contaminated needles. Yet, many years later, our nation's prevention efforts ignore these sound recommendations and instead remain timid and undirected.

Studies of the populations most heavily affected by the epidemic have repeatedly demonstrated that prevention initiatives lead to substantial changes in self-reported sexual behavior. This research indicates that prevention programs that address sexual behavior are most effective when they provide explicit information in a clear, culturally sensitive language, are ongoing, assist individuals in developing sexual negotiation skills, and are administered by members of the target population.

Research confirms that it is also possible to reduce the rate of new infections from needle sharing. According to studies, drug treatment programs provide an ideal site for HIV prevention services. Studies of state efforts to reform restrictive needle access laws have correlated such initiatives with marked declines in risk behavior. Likewise, dozens of scientific studies, many of them sponsored by the federal government, have demonstrated that needle exchange programs reduce HIV infection rates without increasing drug use.

While such powerful evidence demands a robust and energetic response, the federal government has responded with meekness. The epidemic's annual price tag in medical care and lost productivity is in the tens of billions of dollars, yet the federal government devotes a mere $___ million toward programs to prevent HIV transmission. When medical costs are included, HIV prevention has declined as a percentage of government AIDS-related spending.

Worse still, the Administration makes poor use of its limited investment in HIV prevention. The Administration has maintained outdated restrictions on the ability of federally-funded HIV prevention programs to provide explicit information to those at greatest risk, leading HIV prevention educators to censor themselves with an eye to retaining their funding rather than providing the most effective prevention message possible. Moreover, rather than ensure that scarce prevention funds actually go to those in greatest need, the Centers for Disease Control and Prevention inadequately monitors the public health uses to which federal HIV prevention funds are put by state and local health departments. Consequently, one can have little confidence that limited prevention dollars target those at greatest risk and support interventions shown to reduce risk behavior.

Perhaps most dismaying is the continued prohibition on federal funding for needle exchange programs. Fifty percent or more of new HIV infections are traceable to substance use. The Secretary has had the legal authority to lift funding restrictions with a stroke of the pen, yet she has failed to do so. Moreover, the Secretary expended little effort to educate the American public about needle exchange or to build political support for such programs. Although there currently exists a temporary Congressionally-imposed moratorium on exercise of the Secretary's authority to waive funding restrictions and needle exchange, the President should nonetheless

show leadership on this issue by immediately certifying the public health utility of this life saving intervention.

Twenty-five percent or more of all new infections occur among individuals under the age of 22. Nonetheless, the CDC's effort to educate youth regarding HIV remains uncoordinated and unevaluated. Rather than address the reality of adolescent sexuality and drug use, our nation's leaders instead too frequently choose denial or hide behind reports that merely chronicle the loss of young lives.

In 1996, President Clinton challenged the nation to reduce the number of new HIV infections each year until there were none. Sadly, no coherent plan exists for achieving this noble objective. In the absence of bold leadership on the part of the Administration, the nation stands little chance of reducing the epidemic's burden in future years.

Research Subcommittee

The President's is to be highly commended for his leadership in efforts to begin the work of developing an AIDS vaccine. The President's announcement of the goal of an AIDS vaccine within a decade in May, 1997, and the focus on an AIDS vaccine during the G-7 meeting is unsurpassed, greatly appreciated and acknowledged worldwide. But, there is much more that must be accomplished. The Council's recommendations for comprehensive planning and coordination of all Federal efforts, collaboration with the private sector and the international community, the development of an independent AIDS vaccine initiative, a significant and sustained increase in funds from NEW sources and the convening of a public-private AIDS vaccine consultative forum by the Vice-President are still being reviewed and addressed. (ALTERNATIVE: Remaining to be addressed are the Council's prior recommendations for (1) a significant and sustained increase in funding for AIDS vaccine development, (2) a coordinated and comprehensive involvement by all relevant Federal agencies in the effort, (3) close collaboration with the private sector, international community and independent vaccine initiative and (4) the convening under the Vice-President's auspices a public-private AIDS consultative forum.)

The Food and Drug Administration (FDA) is to be commended for its efforts to address some of the issues surrounding gender as recommended by the Council. The Council still needs a follow up report from the FDA on the status of the gender accrual analysis by drug sponsors and the status on dissemination of the guidelines regarding participation of pregnant women in clinical trials. The Council has also been concerned about the lack of data on the effects of HIV therapies in children. We appreciate the FDA's efforts in seeing that labeling of marketed prescriptions drugs includes pediatric data. However, we are still awaiting our requested review of the number of children actually enrolled in NIH-sponsored clinical trials.

The President and Vice-President have continued to support the recommendation for a coordinated Federal approach for HIV/AIDS research through support for the Office of AIDS Research (OAR), including staunch advocacy for a consolidated budget for AIDS research at the

NIH. A consolidated budget for OAR is a Congressional responsibility which has not been achieved.

The Council's three recommendations on microbicide research, approved in December 1995, have not yet been fully addressed. No new funds have been allocated for microbicide research, no new full-time equivalents (FTEs) have been designated to this effort, no new Requests for Applications (RFAs) have been issued, nor has a public health consensus panel to assess the efficacy of available spermicides and other licensed products has not been convened.

Our recommendation to create mechanisms for the rapid translation of breakthrough findings into clinical practice has been partially addressed by the NIH in the area of biomedical research. Several approaches now exist. However, in the area of behavioral and social science, creative mechanisms need to be developed that facilitate rapid translation of these research findings. It is the Council's intent to further address this issue in the future.

Services Subcommittee

HIV/AIDS requires extensive medical care. Access to such care beginning as soon as possible after diagnosis is essential and can often result in greatly extending both length and quality of life for those infected. HIV/AIDS medical care is also expensive, and therefore for those without adequate health insurance or significant personal resources often unavailable. The Administration's proposal for universal health insurance would have ensured such care for most HIV-infected Americans. Unfortunately, the Congress rejected that proposal. As a result, we are left with a piecemeal system of health care in which many do not have access to basic primary medical care or the new therapies which offer them the best chance for long term survival. Medicaid, which now covers about 53% of AIDS treatment and the Ryan White CARE Act are the existing programs through which most HIV/AIDS care is currently provided.

Since July, 1996, the Committee has urged the Administration to review existing programs and begin developing new approaches for providing primary medical care and access to these promising new combination drug therapies. A year ago, the Committee heard from HHS that it would develop new treatment guidelines. We advised HHS then, and the President formally in our December, 1996, Council recommendations, to take those steps necessary to ensure that new policies were developed, and funding made available, that would make these life-enhancing, and perhaps life-saving, therapies available to all those who need them, in accordance with those guidelines. In particular, we focused on the following actions:

1) Leadership On Funding for HIV Treatment, Care and Housing Services

The President's budget, which is released each year in early February, is a reflection of the Administration's values and priorities. In 1997, the Council was deeply concerned that the President's FY 98 budget request recommended no increase for the AIDS Drug Assistance Program (ADAP), and only modest increases for primary medical care and other critical support

services through the Ryan White CARE Act, and Housing Opportunities for People with AIDS Program (HOPWA). Recent reports of a 23% decline in AIDS deaths between 1995 and 1996 obscures the corresponding 11% increase in the number of people living with AIDS during this same period, many of whom are in need of critical services if they are to benefit from promising new therapies. The Council is looking to the President's FY 9 budget request for a clear indication that the Administration understands both the continuing gravity and urgency of the epidemic and is committed to providing the greatest possible funding support.

2) **Expand Medicaid coverage**. For thousands of people with HIV/AIDS, Medicaid provides their only avenue for primary medical care. Medicaid eligibility is now "triggered" by the on-set of disability, but the new therapies are recommended as a means of *slowing disease progression* and thereby *avoiding* disability. Therefore, the current Medicaid eligibility system is seriously out of alignment with the recommended standard of care for the treatment of HIV disease. Early access to the new therapies with supportive medical and social services is a not only a humane policy, but also, we believe, over the long-term, a cost-effective strategy, based on the possible delay or reduction of expensive hospital and other costs associated with disease progression. Also, many people taking the new therapies are leaving disability income supports and becoming fully employed, tax-paying citizens. Further, unlike the AIDS Drug Assistance Program within the Ryan White CARE Act, which covers only drug costs, Medicaid covers associated primary medical care costs. Moreover, since Medicaid is a needs-based entitlement, rather than subject to special annual appropriations, as is Ryan White, availability of the new drugs and associated medical services is driven by treatment needs, and not by annual appropriations battles.

This past Spring, Vice President Gore called for HHS to explore and report back to him within 30 days the feasibility of expanding Medicaid coverage to cover early intervention HIV therapies. Many dedicated public servants within HHS are working diligently to find a means of expanding Medicaid eligibility, and we commend their efforts. We are particularly encouraged that HCFA has been working closely with the AIDS community and outside policy experts to attempt to develop a viable, cost effective, ethnically appropriate mechanism to provide such expansion. However, we have been deeply disappointed by the apparent absence of personal leadership on this issue from HHS Secretary Shalala. In a recent meeting attended by Council members, the Secretary suggested the possibility of proposing increase support for ADAP. , an option which engenders some skepticism since it was Congress, not the Administration, that proposed increased ADAP spending in the 1998 federal budget, and the Secretary has not committed to making this a top priority either for her or the Administration. Because the quality of life and life itself is at stake for so many thousands of people with HIV/AIDS, we will continue to press hard for Administration leadership

3) **Reduce the cost of the therapies**. The Administration, in conjunction with state AIDS and other public health administrators, and with effective pressure from the advocacy community, have employed, with some success, a number of strategies to bring down the cost of the new combination drug therapies. Also, Vice-President Gore raised the issue in his meetings with the

pharmaceutical industry. We believe the Administration is making a sincere and thoughtful effort to try to bring the cost of therapies down, but further efforts is needed to achieve this goal.

4) Monitor Access to These Therapies and Associated Medical Services in Private Managed Care Health Systems. It has been feared (and in many cases, documented) that people with HIV/AIDS and other complex, disabling conditions would not be able to have access to needed drugs and specialists under managed care systems. The President's Advisory Commission on Consumer Protection and Quality in the Health Care Industry has just released its recommendations, which have been endorsed by the President. These recommendations are sensitive to the special needs and circumstances of people with HIV/AIDS, and are an important first step in assuring that people with HIV/AIDS continue to have access to the new therapies and associated medical services through their managed care providers and/or insurers. We commend Secretaries Herman and Shalala and members of the Commission for this sensitivity and look forward to working with them to ensure implementation of these recommendations. We urge the President to aggressively pursue legislative implementation of the Commission's recommendations.

5) A National Policy Dialogue on How to Provide Comprehensive, Early HIV Care. The Ryan White CARE Act has been a triumph of community and federal responsiveness (on a strongly bipartisan basis), providing critically needed support for a wide range of services for many people with HIV/AIDS, as well as ancillary training, technical assistance, and other support. However, recognizing a shifting in the need for such services for some, the impact of the new drug therapies, and also that many who continue to need Ryan White services are still unserved because of the lack of sufficient appropriations, last December the Council recommended a national dialogue on how, over the long term, the federal government should structure, and pay, for medical and support services for people with HIV/AIDS. Despite significant efforts to promote a formal structured dialogue, progress has stalled and it is not clear how HHS plans to proceed. The changing nature of the epidemic and the need for a comprehensive review of the governmental response demand that such an effort be undertaken at the earliest possible date with active participation of all affected parties.

Discrimination Subcommittee

The Council has formally recommended that mandatory HIV testing by and/or discriminatory policies of the U.S. Foreign Service, the Peace Corps, the Job Corps, the State Department and the military be rescinded unless justified by a compelling public health rationale. During its meeting with the President two and one-half years ago, the Council raised this issue and the President responded supportively. However, to date, only the Job Corps has revised its policy. It changed from special mandatory testing to routine testing for HIV and now provides

requisite counseling and care for those testing HIV positive, regardless of whether they are subsequently accepted as students. This exemplary action by the Job Corps should be commended. The remaining federal agencies targeted by the recommendation have failed to respond in any manner, either to change their policies or to offer any rationale for their continuation. The President should not accept this arrogant evasion of the recommended review of such discriminatory policies.

Additionally, the Center for Disease Control and Prevention has not yet addressed its discredited and discriminatory guidelines concerning HIV-positive health care workers despite clear scientific evidence of their invalidity and repeated promises to the Council that such review would be undertaken.

The moral suasion of the President's vocal condemnation of prejudice-based discrimination is severely undercut by this failure by the federal government to take necessary remedial action regarding its own discriminatory policies.

Prisons Subcommittee

HIV disease has demanded a re-evaluation of the ways in which we have traditionally approached public health. For this reason, the Subcommittee on Prison Issues has examined a number of issues affecting prisoners with HIV and AIDS. Since 1990, HIV and AIDS has been the **second** leading cause of death in prisons. The incidence of AIDS in prisons is six times the incidence in the general population. For many incarcerated persons, prison may be their first contact with medical and psychosocial interventions as well as their first opportunity for alcohol and drug treatment. Therefore, prisons provide an ideal environment for prevention and education efforts. A prisoner's health status **upon returning** to society has a direct bearing on the health of the communities into which they return. A strong investment in HIV prevention and care for incarcerated individuals would be a significant barrier against the spread of HIV.

Information from the Department of Justice concerning health care policy in prisons has been useful; however, the information we have received from the Federal Bureau of Prisons has been incomplete and lacking the substance necessary to reassure us that the well-being of inmates in our nations prisons is not at risk. Information from the Department of Defense concerning military prisons and brigs was also requested, but has not yet been received. A number of concerns outlined in our 1996 report have not yet been addressed. And, many appropriate recommendations from the National Commission on AIDS have not yet been implemented.

Since most incarcerated individuals do not remain incarcerated forever, discharge planning for inmates with HIV/AIDS is essential. Pre-release case management and discharge planning are important in assuring that HIV-infected inmates who have been released or paroled have access to the broad range of services needed to make a healthy and successful transition back into their communities. We continue to believe that the ABA standards for compassionate release should be reexamined as an alternative to the current Federal Bureau of Prisons guidelines.

During incarceration, inmates must have access to comprehensive and current medical therapy. It is our understanding that Medical Standards of Care include all FDA-approved treatment modalities. Appropriate use of these therapies needs to be closely evaluated. Federal prisoners should have access to compassionate use therapies which are proven efficacious, but not yet FDA-approved. We want to ensure that HIV treatment follows the current Medical Standards of Care recommendations.

The link between HIV and substance abuse has been clearly established, yet access to essential substance use interventions continues to be variable among institutions. Federal officials report that "inmates who volunteer for treatment are admitted into residential substance abuse programs in sequential order based on release date." (10/15/97) While we applaud this effort, we encourage the Federal Bureau of Prisons to evaluate waiting periods and expand programs to accommodate all inmates seeking treatment. In addition, discussions should continue on inmates' access to clean substance use paraphernalia.

Although Federal officials responded to our queries on protective barriers, they remain extremely resistant to changing their current policy which states "condoms and/or dental dams are not medically necessary for use other than during sexual activity and therefore are not authorized." (7/8/97 & 10/15/97). We feel that this approach is short-sighted. Nor are we persuaded by the concern that access to protective barriers would "create an environment in which control would be difficult." (BoP Conference call 10/14/97). The transmission of HIV and other STD's in prison underscores the fact that sexual behavior is indeed occurring; therefore, this policy should be reconsidered and successful models using protective barriers should be examined.

Despite the policies and procedures developed by the Federal Bureau of Prisons, testimony from current and former inmates reveals that these policies are not administered evenly and uniformly. We agree with the Bureau of Prison's claim that "Offenders are incarcerated AS punishment, not FOR punishment." We are concerned that HIV in correctional settings may not be receiving the attention it deserves. We remain committed to a stronger investment in HIV prevention and care for incarcerated individuals. We believe that this commitment would be a significant barrier against the spread of HIV disease in all of our communities.

International Subcommittee

The global AIDS crisis constitutes a direct threat to the economic and strategic interests of the United States. In light of the ever-worsening global HIV epidemic, the Presidential Advisory Council is disappointed at the apparent failure of the Department of State to conduct an evaluation of the successes and failures of its 1995 "International Strategy on HIV/AIDS". The strategy was developed and issued in 1995 and constituted a two-year plan. It should have been thoroughly assessed, and a current international strategy should have been promptly developed. The global AIDS crisis requires the immediate and consistent attention of the Department of State and the President.

Additionally, insofar as the United States Agency for International Development constitutes the primary U.S. effort to respond to the international AIDS crisis, the Council is similarly concerned that the President has failed to seek increased appropriations for USAID from Congress. The Council emphatically urges the President to request emergency funding for USAID to permit the Agency to immediately increase its global efforts in response to the international explosion of AIDS and HIV. We also strongly urge the President and Secretary of State Albright to consistently and affirmatively reestablish the United States' commitment to lead a global response to the AIDS pandemic.

The Council urges the President to meet with Dr. Peter Piot of UNAIDS at the earliest opportunity to discuss the global AIDS crisis and role of the United States.

AIDS generally

Richard Socarides 10/09/97 09:41:29 AM

Record Type: Record

To: Sandra Thurman/OPD/EOP, Bruce N. Reed/OPD/EOP, Christopher C. Jennings/OPD/EOP, Elena Kagan/OPD/EOP

cc:
Subject: NC5090: Members of AIDS Panel May Resign

---------- Forwarded by Richard Socarides/WHO/EOP on 10/09/97 09:36 AM ----------

rwockner @ netcom.com
10/09/97 03:47:00 AM

Record Type: Record

To: Stuart D. Rosenstein, Richard Socarides

cc:
Subject: NC5090: Members of AIDS Panel May Resign

By LAURAN NEERGAARD

WASHINGTON (AP) - Several of President Clinton's AIDS advisers say they are considering resigning to protest the White House's refusal to spend federal money on buying clean needles for drug addicts.

Some members of the Presidential Advisory Council on AIDS said Wednesday they also are upset the administration has not implemented other council recommendations.

``I think it's fairly serious,'' Dr. Scott Hitt, a Los Angeles physician who chairs the 30-member council, said of the resignation threats.

Leading the protest is council member Robert Fogel, a Chicago lawyer and Clinton fund-raiser. He said Wednesday he plans to seek a vote on the resignation at the council's next meeting in December.

``Somebody up there is thinking more about politics than health,'' Fogel said. ``If they're not going to listen to us and do the right thing, I for one, and a number of other people on the council, can't think of any more excuses or apologies to give on this subject.''

Fogel said ``quite a few'' members of the council would consider resigning, mostly because of anger over needle exchanges.

Hitt has not taken a position on the idea of resigning. But he has met recently with Health and Human Services Secretary Donna Shalala and White House aides in hopes of getting some action before the council issues its evaluation of national AIDS policy in December.

Hitt said the report will have ``some fair but harsh things to say.'' He said he had recently told Clinton in a letter there is ``growing perception that in your second term, HIV/AIDS issues are not the high priority that they were'' previously.

``It's not like we're asking for pie-in-the-sky or perfection in this, but there are a few basic things that need to be done,'' Hitt said in a recent interview.

An administration plan announced this spring to expand Medicaid coverage to HIV patients appears stalled because of budget concerns, Hitt said. The administration also has not lifted restrictions on the content of federal HIV-education materials or revised ``scientifically discredited'' guidelines against HIV-infected health care workers.

``This administration has an extraordinary record in fighting the HIV/AIDS epidemic,'' responded Melissa Skolfield, a spokeswoman for Shalala, who met with concerned council members last month.

An estimated one-third of American adults with AIDS got the killer virus through contaminated needles or sex with injecting drug users. Scientific studies indicate that programs that let addicts exchange used needles for fresh ones cut HIV's spread. The National Institutes of Health has called such needle-exchange programs a powerful weapon against AIDS that has been blocked by politics.

Congress in 1988 outlawed federal money for needle exchanges until there is proof that they don't encourage drug use. That question ``has not been answered conclusively,'' said Skolfield.

Over 80 needle exchanges paid for by private or other nonfederal money already operate in the United States, but AIDS activists say expanding them will require federal money.

Fogel said he was concerned because a House-approved spending bill would strip from Shalala the ability to approve federal money for needle exchanges, even if it's proved they don't encourage drug use.

The Senate version of the bill retains the 1988 language and negotiators for both houses are trying to work out differences on needle exchanges and other differences in the two measures.

``At the moment, we just have to wait to see what happens,'' Fogel said Wednesday. ``If they (administration officials) lose that authority, or retain it but choose not to exercise it, that will be a factor in deciding whether to resign.''

AP-NY-10-08-97 2007EDT

AIDS generally

THE WHITE HOUSE

WASHINGTON

August 6, 1997

MEMORANDUM FOR THE PRESIDENT

FROM: Bruce Reed, Assistant to the President for Domestic Policy
Sandra L. Thurman, Director, Office of National AIDS Policy

SUBJECT: Follow up to the July meeting of the Presidential HIV/AIDS Advisory Council

This memo transmits to you the most recent reports of and a letter addressed to you from the Presidential Advisory Council on HIV and AIDS following its meeting of July 25-26.

The primary focus of the Council's meeting was to review the progress of the Administration regarding previous recommendations in order to "assess both movement on issues and the performance of key Administration officials." Their concerns are expressed in the letter addressed to you (attached) regarding your personal committment to the issue, and the perception of a lack of commitment from certain Administration personnel in your second term.

Their frustration was characterized by a motion put forth for the Council to resign *en masse* if two issues they consider "easy ones" are not resolved by their next full meeting in December: (1) action by Secretary Shalala to lift the ban on federal funding of needle exchange and (2) removal of previously identified discriminatory policies within the Executive Branch. The motion was subsequently withdrawn with the condition that it be placed on the agenda for the December meeting.

In summary, the Council will be looking for Administration leadership on the following:

- Prioritization of AIDS programs in budget negotiations (the FY 1998 budget agreement did not include any AIDS programs under "protected" status, so Council members are closely scrutinizing Administration positions in future budget negotiations);

- An articulated strategy for funding expanded access to new therapies and related medical care and support services (the recently issued HIV treatment guidelines, which recommend antiviral therapy at much earlier stages of HIV disease, were not accompanied by any funding strategy);

- Progress on Vice President Gore's proposed Medicaid demonstration project to allow States to provide the new therapies and limited care to low-income, non-disabled individuals with HIV (currently most get Medicaid based on a determination of their becoming disabled, which may well have been forestalled if the new treatments had been given before disability occurred);

- Secretary Shalala lifting the restriction on federal funding of needle exchange programs (Council members feel that HHS has only moved to protect the Secretary's authority to lift the restriction and not to actually exercise that authority);

- Enhancement of the Office of National AIDS Policy (increased staffing, additional resources and authority to translate White House policy decisions into departmental rules, regulations, and policy directives);

- Progress on the AIDS vaccine initiative; while the Council commends your announcement of developing an effective AIDS vaccine within a decade, they outline some additional issues that the Administration needs to address including:

  * substantive involvement among all relevant federal agencies;
  * mechanisms of collaboration and cooperation between federal agencies;
  * communication, aid, and collaboration with international efforts for vaccine research, development and utilization;
  * facilitation of public-private discussions encouraging cooperation and partnerships among government and industry; and
  * identification of new funding for AIDS vaccine development, though not at the expense of other AIDS-related research.)

The Council is requesting a meeting with you and any appropriate Administration officials. They are preparing a strongly-worded letter for Secretary Shalala expressing their concerns and requesting a meeting.

PRESIDENTIAL

ADVISORY

COUNCIL ON

HIV/AIDS

July 26, 1997

The Honorable William Jefferson Clinton
The White House
Washington, D.C. 20500

Dear Mr. President:

Reauthorization of your Advisory Council on HIV/AIDS and recognition that only 40 months remain in your Presidency offer a valuable opportunity for taking stock of our shared commitment to defeat HIV disease. Securing unprecedented funding for AIDS, establishing the Offices of AIDS Research and National AIDS Policy, convening the White House Conference on HIV/AIDS, developing the first-ever National AIDS Strategy and setting a goal of development within a decade of a vaccine to prevent AIDS have been major milestones in this fight, milestones of which you can be justly proud.

We are concerned, however, about the growing perception that in your second term HIV/AIDS issues are not the high priority that they were during the first term and that certain Administration personnel may not share your personal commitment to these issues.

You clearly articulated in the National AIDS Strategy preamble the six simple, but vital goals necessary to end this epidemic. You have told us publicly and privately that you expect us to give you the truth, unvarnished, as we perceive it. In that spirit, we constantly strive to recognize both the accomplishments and inadequacies resulting from Administration actions and to ensure that perceptions of those actions mirror as closely as possible their realities.

As you stated in the opening words of your national strategy, "the epidemic of HIV and AIDS constitutes a public health crisis of unprecedented proportions." The challenges facing us require maintaining the urgency of the "crisis," while pursuing the permanent systemic changes necessary to deal with HIV/AIDS long after you leave office.
If we are to convert the promise of your words to reality for those affected by HIV disease, much remains to be done during the next 40 months.

808 17th Street, N.W., Suite 820

Washington, DC 20006

The Council is currently reviewing the progress made toward addressing our earlier recommendations, and expects to complete a report in December that will assess both movement on issues and the performance of key Administration officials. During that evaluation process, several critical issues of concern have been raised:

- The Council had previously urged that HIV prevention and housing programs be added to the Administration's list of "investment priorities" that already covered HIV research and care programs. However, the FY 1998 balanced budget agreement with the Congress, is perceived by many as a step backwards in that it fails to maintain the protected status for any AIDS programs. If, in the future, that decision results in AIDS programs being forced to compete with countless other discretionary programs for sharply diminished funding, accomplishment of your stated goals will be seriously jeopardized.

- Acknowledging the dramatic changes in medical management of HIV disease, HRSA recently issued HIV treatment guidelines that recommend antiviral therapy at much earlier stages of HIV disease. Unfortunately, no strategy has been articulated for funding the requisite dramatic expansion in access to HIV therapies and the primary medical care to facilitate that access. The Administration's FY98 budget, for example, failed to propose any additional spending for AIDS Drug Assistance Programs (ADAP) despite urging from 12 Governors of your strong support for adequate funding and also proposed inadequate funding increases for primary medical care through the Ryan White CARE Act. Presidential leadership will be essential to providing adequate resources for this vital safety-net program.

- In April, Vice President Gore announced a major Administration initiative, ordering a study within 30 days of a Medicaid demonstration project to allow States to cover low-income, non-disabled individuals with HIV. The proposed Medicaid expansion, long sought by the AIDS community, would address a serious deficiency in the Medicaid program that has generally required that adults with HIV infection become fully disabled before becoming eligible for coverage. That approach clearly impedes effective early intervention. Although the Vice President proposed only to study, rather than to implement immediately the proposed Medicaid expansion, his comments, which received widespread media attention, clearly indicated an intention to bring this proposal to fruition. Since that announcement, however, there has been little visible progress in making this proposal a reality. Clear direction to take all necessary action to quickly implement this initiative is essential.

- As an essential component of a strategy to achieve your goal of "reducing the number of new infections each and every year until there are no more new infections," your Council has strongly recommended a number of steps to deal with the role of injection drug use in the spread of HIV, including lifting the ban on federal funding for needle exchange programs. Five months ago, senior officials of the Department of Health and Human Services gave public assurance that the Administration intended to study the ban, with a view toward lifting current funding restrictions. However, a strategy for lifting the ban has not yet been developed. Little, if any, clear progress has been made on this crucial issue, notwithstanding the fact that tens of thousands of Americans become infected each year due to contaminated needles and that the science supporting the efficacy of needle-exchange programs is clear. Other potentially promising prevention strategies also remain mired by inaction on the part of Secretary Shalala and HHS.

- In the past, the Council was able to benefit from staff support at the Office of National AIDS Policy to shepherd Council recommendations through the federal bureaucracy. When announcing the appointment of your new Director of the Office of National AIDS Policy you pledged to provide that office with the resources necessary to accomplish your stated goals. The long-term, complex reality of HIV/AIDS will require the institutionalization of your Administration's policies. Systemic change is crucial. In order to ensure such change, adequate attention must be given to translating White House policy decisions into departmental rules, regulations, and policy directives. Staff within the Executive Office of the President must be charged with initiating and monitoring on a constant basis that effort. Based on our recent experiences, current staffing of the ONAP office is insufficient to accomplish your goal. Additional resource commitments and authority must be provided.

- The Council commends your declaration on May 18, 1997 of the goal to develop an effective AIDS vaccine within a decade. This bold step inspired many around the world. To achieve this goal, additional issues must be addressed: all relevant agencies within the federal government must be substantively involved in the AIDS vaccine effort; mechanisms of collaboration and cooperation should be implemented among these federal agencies; the U.S. Government must establish means to communicate, aid, and collaborate with international efforts for vaccine research, development and utilization; the government should facilitate public-private discussions to encourage cooperation and partnerships among government and industry; and specific sources of new funding for AIDS vaccine development must be identified.

Action on these items is needed immediately not only to continue our long national fight against the disease but to reassure the AIDS community that your Administration still sees HIV/AIDS as the important priority you so clearly made it during your first term. We would like the opportunity to meet soon with you and any appropriate Administration officials to best determine how to advance our common agenda.

Sincerely,

R. Scott Hitt, M.D.
Chair, on behalf of the members of
the Presidential Advisory Council
on HIV/AIDS

Presidential Advisory Council on HIV/AIDS

Stephen N. Abel, D.D.S.
Mr. Terje Anderson
Ms. Regina Aragon
Ms. Judith Billings
Ms. Mary Boland
Mr. Nicholas Bollman
Mr. Tonio Burgos
Jerry Cade, M.D.
Rabbi Joseph Edelheit
Mr. Robert Fogel
Ms. Debra Fraser-Howze
Ms. Kathleen Gerus
Ms. Phyllis Greenberger
Nilsa Gutierrez, M.D.
Mr. Bob Hattoy
Mr. B. Thomas Henderson
R. Scott Hitt, M.D., Chair
Michael Isbell, J.D.
Mr. Ronald Johnson
Mr. Jeremy Landau
Alexandra Mary Levine, M.D.
Mr. Steve Lew
Ms. Helen H. Miramontes
Rev. Altagracia Perez
Michael Rankin, M.D.
Mr. H. Alexander Robinson
Ms. Debbie Runions
Mr. Sean Sasser
Mr. Benjamin Schatz
Mr. Richard W. Stafford
Ms. Denise Stokes
Mr. Charles Quincy Troupe
Bruce Weniger, M.D.

COMMUNITITES OF AFRICAN AND LATINO DESCENT
COMMITTEE ACTION PLAN
August 4, 1997

1. A panel on issues concerning Communities of Color is being assembled for the December Meeting.

DISCRIMINATION SUBCOMMITTEE ACTION PLAN
August 4, 1997

1. The President should be informed directly by Sandy that the policy of mandatory testing and exclusion continues by the Federal Government and that the Council is dismayed. Bruce Reed should be phoned (by Sandy or Scott) and asked to pull together a high-level meeting of agency heads in those agencies that have discriminatory policies, and be told ideally, to change their policies.

2. We want the HIV positive healthcare worker issue on the agenda for a Shalala meeting.

3. We'd like Daniel to set up a meeting with the new Justice Department Civil Rights Chief to discuss strong ADA enforcement and to support dedicated staffing in Sandy's office.

INTERNATIONAL COMMITTEE ACTION PLAN

August 4, 1997

1. The Council unanimously expressed its support for continued U.S. funding and cooperation with UNAIDS.

   - We should confirm that USAID receives the message, and consider speaking with the USAID staff responsible for cooperating and assisting UNAIDS.

   - We must follow up with USAID on our request for a flow chart with names of personnel responsible for USAID global HIV/AIDS programs.

   - We should continue to encourage USAID to support the creation of PACHA-type councils in foreign nations.

2. The Committee requested that the Department of State report on its assessment of achievements of its 1995 global HIV/AIDS plan, and provide a draft of its 1997 strategic plan.

3. In conjunction with the Research and Discrimination Committees, we should monitor the Administration's action on the vaccine initiative and elimination of discrimination in U.S. government foreign service agencies.

PRISONS ISSUES SUBCOMMITEE ACTION PLAN
August 4, 1997

General Interim Assessment

- Analysis and development of recommendations is complicated by the many strata which exist in the correctional system. Thus much of our attention is focused on the Federal system, however, this represents < 10% of inmates.

- Response from Justice Department is timely; from HHS incomplete requiring dialogue; from Federal Bureau of Prisons exceptionally slow and to date unsatisfactory.

Issues on Agenda

- Full analysis of bullets from December '96 meeting. Analysis pending while we await response from Dr. Moritsugu.

- Compassionate Release. Response from Bureaus recently received, analysis pending.

- Discharge Planning. Responses from agencies recently received, analysis pending.

- Standards of Care. Analysis of how standards are being addressed in systems. Should obstacles exist, how can we overcome them?

- Protective Barriers. Analysis of response pending. Copies of PS5270.07 and PS6100.01 (statutes prohibiting condoms, risk-reduction devices) have been requested.

- Substance Abuse Treatment and HIV Infection. Responses being analyzed.

Action Plan

1. Very recent response to our April recommendation require Subcommittee to confer regularly over the next months.

2. Conference call planned with Dr. Moritsugu on July 29th to address unanswered bullets of December 1996.

3. Prison site visit along with meeting with Community Groups to address other issues such as Women with AIDS; Psychosocial Counseling; Education and Training; Clinical Trials.

4. Meeting with HRSA for discharge planning models for prisoners and utilization of AETC.

5. Meeting with Attorney General Reno should obstacles to obtaining timely information continue.

6. Consideration to Summit Meeting on AIDS in Prison with Interagency Federal Reps/State/Community representation. If not a summit, then a request that ONAP bring together key players for open discussion.

7. Reintegration of key issues back into appropriate Committees.

Prevention Subcommittee Action Report
August 4, 1997

1. LETTER: Follow-up letter to CDC
   RE: Atlanta meeting and Issus discussed
   DRAFT: Alexander Robinson
   DUE: 8/8

2. CDC ADVISORY COMMITTEE: Alexander Robinson will represent PACHA Prevention Subcommittee (Helene Gayle request)
   DATES OF NEXT CDC ADVISORY COMMITTEE MEETING: 10/16-17, Atlanta, GA

3. MEETING: Participate in Shalala Meeting
   (Meet with HHS staff prior to meeting Shalala meeting (ie.Thurman, Martin, etc.)

4. Shalala Press Strategy (deferred due to 7/30 Process Conference Call)

5. Finish Assessment Process of Prevention Recommendations
   DRAFT: Mike Isbell
   DUE: 8/18

6. LETTER: CDC
   RE: Future of Surveillance
   DRAFT: Alexander Robinson
   DUE: 8/8

7. LETTER: Janet Reno
   RE: Model Drug Paraphernalia Law and Status Report
   DRAFT: Terje Anderson
   DUE: 8/8

8. LETTER: General McCaffrey/ONDCP
   RE: Requesting Meeting
   DRAFT: Terje Anderson
   DUE: 8/8

9. LETTER: Nelba Chavez/SAMHSA
   RE: Requesting Meeting
   DRAFT: Terje Anderson
   DUE: 8/8

RESEARCH SUBCOMMITTEE ACTION PLAN
August 4, 1997

Vaccine Recommendation Action Plan

By 10/1/97:

1. Conference Calls: IAVI, CDC, DOD, UNAIDS, some non-government vaccine researchers.

   Purpose: Feedback on April 1997 Recommendations
   What is the impact?
   Next steps for the Council?

2. Private dialogues with Bill Paul (phone call, conference call, and/or face-to-face).

   Purpose: Expand on NIH's role in vaccine development
   What is the status of new Vaccine Center?
   Will the Center control the whole $150 million?
   Relationship to OAR? NIAID?
   Where will study sections be located?

3. Dialogue with David Baltimore (phone call, conference call)

   Purpose: The Advisory Committee's role
   Relationship of Advisory Committee to new Center?

4. Vice President: Urge V.P. to meet with biotech firms (vaccine). No government people; only Sandy Thurman, V.P.

   Merck, Wyeth, SmithKline, Pasteur, Vaxgen, Chiron, Therion, Acrogen, Virus Research Institute

5. Begin drafting document:

   a. Key issues for main summary, with future plans

   b. Include:

      1. Rationale
      2. Clarification
      3. Assessment of effort, highlighting gaps
      4. Future steps

SERVICES SUBCOMMITTEE ACTION PLAN
August 4, 1997

DRAFT

Next action steps, in relation to the following priorities:

1. **Medicaid expansion** (lead: Bollman)

- Coordinate effort (with ONAP, AIDS Action Council, and others) to secure release of HHS feasibility report, perhaps involving a meeting directly with Secretary Shalala.
- Direct engagement with the Vice President and his staff on this issue.
- Determine an appropriate and effective PACHA approach to states to encourage choosing the expansion option.

2. **Cost of pharmaceuticals issue** (lead: Lew)

- Status report from HRSA, updating the April HRSA response to the PACHA December recommendation. This addresses various bulk purchase and negotiated price strategies.
- FASA was repealed; little hope in the near future.
- Status report from NASTAD.
- Follow up with the Vice President's office on other pharmaceutical cost reduction strategies, such as reducing the cost of production, reducing profit margins to reasonable levels (jawboning), etc.
- Consult treatment advocates on Service Committee conference call.

3. **Managed care/quality of care outcomes for people with HIV/AIDS** (lead: Bollman)

- Review draft report of White House Task Force on Consumer Protection and Quality of Care.
- Prior to that, ask Task Force E.D. or Deputy Director (Sorian) and Task Force member Dr. Sandra Hernandez to give the Committee a preview on one of our conference calls.
- Look into finding other written reports and data to share with the committee as suggested by Regina Aragon.

4. **Keystone Dialogue** (lead: Anderson, Bollman, Lew)

- Await results of August 7 meeting to determine further action. Above PACHA members to participate in meeting and disseminate information.

5. **Transition to Employment** (lead: Edelheit)

- Request conference call discussion with leaders of working groups formed from the New York "Return to Work" meeting.

- Request informal meeting with DOL Secretary Alexis Herman to discuss opportunities to make employment and training and placement funds available to people with HIV/AIDS able to work (funds such as Vocational Rehabilitation, Joint Training Partnership Act, proposed Employment and Training block grant funds, etc.).

Preview of upcoming issues:

1) Begin to address FY 1999 budget issues for CARE, ADAP, housing (HHS will be submitting its budget to OMB by the December meeting and we will want to engage sooner to affect the agency request - this could be done by conference call) and President's State of the Nation address. Prevention and research addressed in other committees.

2) Summers will prepare a memo on AIDS housing issues and opportunities, to be discussed on a Services Committee conference call.

AIDS-general

PRESIDENTIAL
ADVISORY
COUNCIL ON
HIV/AIDS

July 26, 1997

The Honorable William Jefferson Clinton
The White House
Washington, D.C. 20500

Dear Mr. President:

Reauthorization of your Advisory Council on HIV/AIDS and recognition that only 40 months remain in your Presidency offer a valuable opportunity for taking stock of our shared commitment to defeat HIV disease. Securing unprecedented funding for AIDS, establishing the Offices of AIDS Research and National AIDS Policy, convening the White House Conference on HIV/AIDS, developing the first-ever National AIDS Strategy and setting a goal of development within a decade of a vaccine to prevent AIDS have been major milestones in this fight, milestones of which you can be justly proud.

We are concerned, however, about the growing perception that in your second term HIV/AIDS issues are not the high priority that they were during the first term and that certain Administration personnel may not share your personal commitment to these issues.

You clearly articulated in the National AIDS Strategy preamble the six simple, but vital goals necessary to end this epidemic. You have told us publicly and privately that you expect us to give you the truth, unvarnished, as we perceive it. In that spirit, we constantly strive to recognize both the accomplishments and inadequacies resulting from Administration actions and to ensure that perceptions of those actions mirror as closely as possible their realities.

As you stated in the opening words of your national strategy, "the epidemic of HIV and AIDS constitutes a public health crisis of unprecedented proportions." The challenges facing us require maintaining the urgency of the "crisis," while pursuing the permanent systemic changes necessary to deal with HIV/AIDS long after you leave office.

If we are to convert the promise of your words to reality for those affected by HIV disease, much remains to be done during the next 40 months.

h Street, N.W., Suite 820
Washington, DC 20006

The Council is currently reviewing the progress made toward addressing our earlier recommendations, and expects to complete a report in December that will assess both movement on issues and the performance of key Administration officials. During that evaluation process, several critical issues of concern have been raised:

- The Council had previously urged that HIV prevention and housing programs be added to the Administration's list of "investment priorities" that already covered HIV research and care programs. However, the FY 1998 balanced budget agreement with the Congress, is perceived by many as a step backwards in that it fails to maintain the protected status for any AIDS programs. If, in the future, that decision results in AIDS programs being forced to compete with countless other discretionary programs for sharply diminished funding, accomplishment of your stated goals will be seriously jeopardized.

- Acknowledging the dramatic changes in medical management of HIV disease, HRSA recently issued HIV treatment guidelines that recommend antiviral therapy at much earlier stages of HIV disease. Unfortunately, no strategy has been articulated for funding the requisite dramatic expansion in access to HIV therapies and the primary medical care to facilitate that access. The Administration's FY98 budget, for example, failed to propose any additional spending for AIDS Drug Assistance Programs (ADAP) despite urging from 12 Governors of your strong support for adequate funding and also proposed inadequate funding increases for primary medical care through the Ryan White CARE Act. Presidential leadership will be essential to providing adequate resources for this vital safety-net program.

- In April, Vice President Gore announced a major Administration initiative, ordering a study within 30 days of a Medicaid demonstration project to allow States to cover low-income, non-disabled individuals with HIV. The proposed Medicaid expansion, long sought by the AIDS community, would address a serious deficiency in the Medicaid program that has generally required that adults with HIV infection become fully disabled before becoming eligible for coverage. That approach clearly impedes effective early intervention. Although the Vice President proposed only to study, rather than to implement immediately the proposed Medicaid expansion, his comments, which received widespread media attention, clearly indicated an intention to bring this proposal to fruition. Since that announcement, however, there has been little visible progress in making this proposal a reality. Clear direction to take all necessary action to quickly implement this initiative is essential.

- As an essential component of a strategy to achieve your goal of "reducing the number of new infections each and every year until there are no more new infections," your Council has strongly recommended a number of steps to deal with the role of injection drug use in the spread of HIV, including lifting the ban on federal funding for needle exchange programs. Five months ago, senior officials of the Department of Health and Human Services gave public assurance that the Administration intended to study the ban, with a view toward lifting current funding restrictions. However, a strategy for lifting the ban has not yet been developed. Little, if any, clear progress has been made on this crucial issue, notwithstanding the fact that tens of thousands of Americans become infected each year due to contaminated needles and that the science supporting the efficacy of needle-exchange programs is clear. Other potentially promising prevention strategies also remain mired by inaction on the part of Secretary Shalala and HHS.

- In the past, the Council was able to benefit from staff support at the Office of National AIDS Policy to shepherd Council recommendations through the federal bureaucracy. When announcing the appointment of your new Director of the Office of National AIDS Policy you pledged to provide that office with the resources necessary to accomplish your stated goals. The long-term, complex reality of HIV/AIDS will require the institutionalization of your Administration's policies. Systemic change is crucial. In order to ensure such change, adequate attention must be given to translating White House policy decisions into departmental rules, regulations, and policy directives. Staff within the Executive Office of the President must be charged with initiating and monitoring on a constant basis that effort. Based on our recent experiences, current staffing of the ONAP office is insufficient to accomplish your goal. Additional resource commitments and authority must be provided.

- The Council commends your declaration on May 18, 1997 of the goal to develop an effective AIDS vaccine within a decade. This bold step inspired many around the world. To achieve this goal, additional issues must be addressed: all relevant agencies within the federal government must be substantively involved in the AIDS vaccine effort; mechanisms of collaboration and cooperation should be implemented among these federal agencies; the U.S. Government must establish means to communicate, aid, and collaborate with international efforts for vaccine research, development and utilization; the government should facilitate public-private discussions to encourage cooperation and partnerships among government and industry; and specific sources of new funding for AIDS vaccine development must be identified.

Action on these items is needed immediately not only to continue our long national fight against the disease but to reassure the AIDS community that your Administration still sees HIV/AIDS as the important priority you so clearly made it during your first term. We would like the opportunity to meet soon with you and any appropriate Administration officials to best determine how to advance our common agenda.

Sincerely,

R. Scott Hitt, M.D.
Chair, on behalf of the members of
the Presidential Advisory Council
on HIV/AIDS

Presidential Advisory Council on HIV/AIDS

Stephen N. Abel, D.D.S.
Mr. Terje Anderson
Ms. Regina Aragon
Ms. Judith Billings
Ms. Mary Boland
Mr. Nicholas Bollman
Mr. Tonio Burgos
Jerry Cade, M.D.
Rabbi Joseph Edelheit
Mr. Robert Fogel
Ms. Debra Fraser-Howze
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Mr. Benjamin Schatz
Mr. Richard W. Stafford
Ms. Denise Stokes
Mr. Charles Quincy Troupe
Bruce Weniger, M.D.

August 6, 1997

PRESIDENTIAL
ADVISORY
COUNCIL ON
HIV/AIDS

The Honorable Donna E. Shalala
Secretary
Department of Health and Human Services
200 Independence Avenue
Washington, D.C. 20201

As members of the President's Advisory Council on HIV/AIDS, we are writing to express our urgent concern regarding certain HIV/AIDS-related issues and to request a meeting with you prior to September 30, 1997, to discuss those issues. Such a meeting should serve to expedite resolution of critical, time sensitive issues which currently impede fulfillment of the President's stated goals for ending this epidemic. In the President's words, "[t]o achieve these objectives, we must all stand shoulder-to-shoulder in our fight."

In keeping with the responsibilities assigned to us by the President, this Council, in consultation with leading medical and public health officials and with community-based AIDS groups, has investigated the federal response to AIDS. Following extensive deliberations, the Council has issued recommendations that represent our judgment regarding how best to realize the President's clear commitments and directives regarding AIDS.

Many of those recommendations have been referred for your response. Disappointingly, those recommendations have been, in large measure, either ignored or insufficiently acted upon by the Department of Health and Human Services. Silence on these issues has become increasingly frustrating and detrimental to the partnership necessary for achieving the President's goals.

As part of our continuing assessment of the Administration's response to AIDS, the Council will issue in December another status report to the President. A meeting to discuss outstanding issues of concern regarding HHS policies is urgently required to complete that task. Particular focus on development and implementation of a comprehensive strategy to accomplish the President's goal of "reducing the number of new infections each and every year until there are none" including addressing substance abuse and its effect on HIV transmission, along with both the availability of and access to treatment, is essential to that process.

808 17th Street, N.W., 8th Floor
Washington, DC 20006

Most pressing among those issues on which response has been inadequate are:

- Timely elimination of restrictions on the use of federal funds for needle exchange and failure to exercise the waiver authority granted by Congress, despite clear scientific evidence of the efficacy of and growing public support for such programs.

- Implementation of the Administration's initiative announced over three months ago, to undertake a 30-day study of expanding Medicaid coverage for early intervention therapy for low income HIV infected individuals who have not yet become legally disabled.

- Prioritization in the FY 1999 Administration budget request of funding for AIDS prevention and housing, along with reprioritization for AIDS care and research. In particular, HHS plans for implementing the recently issued HIV treatment guidelines and the requisite expansion of primary medical care necessary to provide access to the recommended therapies.

- Removal of existing restrictions on the content of CDC-supported HIV prevention materials, with the goal of establishing accuracy and appropriateness for the target audience as the sole criteria for assessing such materials.

- Immediate review and revision of the scientifically discredited CDC guidelines covering HIV infected health care workers.

- The specific plans of appropriate HHS agencies for their substantive involvement in what should be an expedited, high-priority, well-financed, coordinated, government-wide effort -- with private industry partnerships and international collaborations -- to achieve the declared goal of an AIDS vaccine within a decade.

- Provision of sufficient resources, consistent with the President's commitment in reorganizing the Office of National AIDS Policy, for accomplishing the President's goals. Such resources are critical to systematic institutionalization of the President's policy decisions through development of departmental rules, regulations and directives, along with appropriate coordination and monitoring.

While the Council's initial recommendations targeted research, prevention and service related topics, specific recommendations relating to the particular needs of communities of color, women, children and adolescents, young gay men, prisoners and international populations are in continual development.

The Council sincerely desires to assist the President and his Administration in achieving prompt resolution of these critical issues in a manner which maximizes the federal government's ability to effectively respond to the HIV epidemic.

Your positive response at your earliest convenience to this request for a meeting will be greatly appreciated. We are available for a preliminary conference call or other appropriate prerequisites to such a meeting at your convenience. Please contact Council Chairman Scott Hitt to follow up. Thank you for your consideration.

Sincerely,

R. Scott Hitt, M.D.
Chair, on behalf of the members of the
Presidential Advisory Council on HIV and AIDS

AIDS - general

AIDS

Q: WHAT IS YOUR POSITION ON THE MAYORS' RESOLUTION IN SUPPORT FOR FEDERAL FUNDING OF NEEDLE EXCHANGE PROGRAMS?

A: Current law prohibits the Administration from authorizing the use Federal funds for needle exchange programs unless there is conclusive evidence that they do not encourage drug use. Although there is strong evidence that indicates that needle exchange programs help reduce the spread of AIDS, we have not concluded our review on whether these programs increase the use of drugs.

We are consulting with HHS and the Office of National Drug Control Policy in this regard. But once again, we are explicitly prohibited from releasing Federal public health dollars until and unless a formal determination is made that the use of these programs does not increase drug use. It is important to point out that local communities remain can and do use non-Federal funds to support such programs.

Q: HOW DO YOU RESPOND TO AIDS ACTIVISTS CALL FOR MORE FUNDING OF PROTEASE INHIBITORS FOLLOWING UP THE HHS-ISSUED GUIDELINES LAST WEEK ON AIDS TREATMENT?

A: The Department is reviewing the budget implications of the new treatment guidelines for the AIDS Drug Assistance Programs (ADAP). We are working with states to determine whether our current budget does enough to help states treat those in need. If it becomes clear that there is a severe shortage in this area than we will -- as we always have -- make every effort to address these problems.

Last year, when we determined we needed more funding for this program to cover the then new protease inhibitor drugs, we sent two budget supplementals to the Hill. My Administration has nearly tripled funding for ADAP since I took office, and my current budget represents an 168 percent increase for Ryan White.

Q: WHY NOT EXPEND THIS KIND OF ENERGY AND RESOURCES ON A CURE FOR BREAST CANCER OR HEART DISEASE OR DIABETES AS IT SEEMS TO FOR AIDS?

A: This Administration has made a strong improving biomedical research an extremely important priority. We have increased investments in biomedical research at the National Institutes of Health by an impressive 16 percent since the I took office.

These additional investments has been used to increase investments in biomedical research in a number of important areas. For example, funding for breast cancer research has increased by 76 percent since 1993 .

AIDS - generally

STATISTICS ON THE AIDS EPIDEMIC

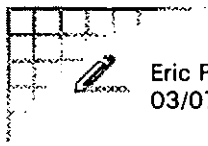
National Trends

- Between 650,000 and 900,000 Americans are living with HIV.
- Since the AIDS epidemic began 500,000 Americans have been reported with AIDS -- 300,000 have died.
- An estimated 40,000 to 60,000 Americans are being infected with HIV each year.
- It is the leading cause of death among Americans aged 25 to 44.
- Women now comprise 14% of people with AIDS. If the current trends continue, an estimated 80,000 children will have been orphaned as a result of this disease by the end of the decade.
- In 1994 alone, 1,000 new pediatric cases of AIDS were reported.
- One in four new HIV infections in the U.S. occur among people under the age of 21. Between 27 and 54 Americans under the age of 21 are infected with HIV each day.
- People of color have been disproportionately impacted by AIDS. As of October 1995, 38 percent of newly reported AIDS cases were with people of color

International Trends

- More than 29 million men, women and children around the world have been infected with HIV -- more than 3 million infections occurring within the last year.
- In 1995, 1.1 million adults and 350,000 children in the world died of AIDS.
- It has been estimated in some countries in subsaharan Africa that life expectancy has decreased by up to twenty years because of the AIDS epidemic.
- In 1992, in South Africa 2% of all women who came in for prenatal treatment were HIV positive and that number is up to 14%.
- Without an effective vaccine, AIDS will soon overtake tuberculosis and malaria as the leading cause of death among persons between 25-44 years of age.

F.6 - AIDS vaccine



Eric P. Goosby
03/07/97 07:15:06 PM

Record Type: Record

To: Bruce N. Reed/OPD/EOP, Elena Kagan/OPD/EOP

cc:
Subject: re: Vaccine Meeting

I attended a meeting today with Nancy-Ann Min and Kevin Thurm looking at the possibilities in the area of vaccine development.

Participants:

Nancy-Ann Min
Kevin Thurm

Outside Participatns:

Harold Varmus, M.D. NIH Director
William Paul, M.D. , Director Office of AIDS Research
Jack Whitescarver, Phd., Deputy OAR
Tony Fauci, M.D., Director NIAID/NIH
David Baltimore, M.D., Coordinator of Vaccine Research, OAR

The discussion explored the potential for the development of an effective vaccine, cost considerations and the potential role the President may take in supporting this effort.

Key Issues Discussed:

* Possible advances in vaccine development:

    1. Simian Immunodeficiency Virus Vaccines are protective in monkeys
    2. New attenuated vaccine developed in Australia may afford an opportunity to develop an effective vaccine with low risk of carcinogenicity
    3. incorporation of the HIV viral genes into the host DNA may be carcinogenic twenty years down the road, this precludes our ability to move rapidly through human trials (too risky, must move very slowly to develop an efficacious vaccine with a high degree of safety)
    4. DNA vaccines; discovered U of Wisconsin, when DNA is injected into study animals it can elicit a strong immune response (immunogenicity). This wasn't thought to be possible 2 years ago. This line of research may prove productive in HIV vaccine research

* The feeling among the scientists was that they cannot put an accurate timeline on the success of the vaccine efforts.,

* They emphasized the need to support the basic research component of the equation in developing potential products that would be of interest to Industry

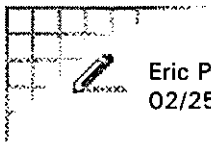
* Harold Varmus, and Kevin Thurm felt the President could promote the area of HIV Vaccine research both domestically and internationally, as part of a long term plan of events that in aggregate brought attention and resources from both the private and public sectors.

* The possibility of an initiative on Emerging Infections (Malaria, Ebola Virus, HIV and TB) was also discussed from an international perspective

FOLLOW UP

Nancy-Ann asked that NIH come back with a plan that would focus on a long term strategy for the President to consider. They will include an analysis of what type of resources may be needed to maximize our ability to take advantage of all scientific opportunities highlighting potential areas of collaboration with the pharmaceutical companies. I was asked to facilitate a more detailed description of the potential scientific products that one might anticipate over a shorter time frame, with added efforts in this area.

Timeline: 5-7 days



Eric P. Goosby
02/25/97 06:12:56 PM

Record Type: Record

To: Bruce N. Reed/OPD/EOP

cc: Elena Kagan/OPD/EOP, Christopher C. Jennings/OPD/EOP, Pauline M. Abernathy/OPD/EOP
Subject: CDC: Death Rate Report

As you are aware there are a number of very optimistic numbers coming out this Friday regarding AIDS Death Rates. The overall message is that the deaths related to AIDS have declined in all high risk groups by approximately 12% in the first 6 moths of 1996 (only data available). HHS has been working on a press release that should be cleared by noon tomorrow. The significance of this is extraordinary and reflects positively on the efforts the Administration has coordinated in the HIV arena. I feel it most specifically reflects the increase in medical infrastructure over the last three years in increases in RWCA funding, in addition to Prevention interventions and therapeutic advances in opportunistic infections . This is something the President can take pride in presenting.

Let me know if this is something you would be interested in putting forward in a written or verbal statement.

thanks,

Eric Goosby

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MMWR AIDS Death Rate Report

The February 28 issue of the Morbidity and Mortality Weekly Report (MMWR) will include an article detailing the latest trends in AIDS cases and deaths. Highlights of that article are:

AIDS Deaths

- Overall, AIDS-related deaths in the U.S. declined 12 percent in the first six months of 1996 compared with the same time period in 1995. This is the first decline in deaths in the history of the epidemic.
- AIDS-related deaths declined in all regions of the country with the biggest declines in the Northeast and West and the smallest in the South).
- AIDS deaths were down among men (15%), gay/bisexual men (18%), and IV drug users (6%).
- AIDS deaths were up among women (3%) and heterosexuals (3%).
- While all races experienced a decline in AIDS deaths, the declines were greatest among Whites (21%), Hispanics (10%), and Asian-Pacific Islanders (6%) and smallest among African-Americans (2%).

AIDS Cases

- The number of Americans diagnosed with AIDS increased by only 2 percent in 1995 versus 1994 (63,000 vs. 61,600).
- The incidence of AIDS cases has been virtually level since 1992 (increasing less than 5% each year).
- Reductions in incidence have been greatest among men, gay/bisexual men, and IV drug users.
- AIDS incidence has been rising among women, African-Americans, and heterosexuals.
- Because of longer life expectancy, the number of Americans living with AIDS increased 10 percent from mid-1995 to mid-1996 to 223,000.

AIDS-generally

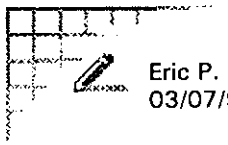
Policy Planning 1/15/97

Priorities

- Access to treatment
- HIVs beyond our borders
- way to prevent infection among drug users (needle exchange progs) or new - auth to do research on this. treatment another way.
- prevention among young people.
- Microbicide - to protect women / instead of condom (better than condoms?? would people stop using them??)

BR - Needle memo?

File - AIDS general



Eric P. Goosby
03/07/97 06:48:24 PM

Record Type: Record

To: Bruce N. Reed/OPD/EOP, Elena Kagan/OPD/EOP

cc: Sylvia M. Mathews/WHO/EOP
Subject: NORA Meeting with John Podesta

Bruce and Elena:

I attended a meeting with the National Organizations Responding to AIDS (NORA and John Podesta yesterday. Following is a brief summary:

Participants:

John Podesta
Maria Echaveste
Toby Donednfeld
Richard Socarides
Marsha Scott
Nancy-Ann Min
Richard Sorian, DHHS

Outside Participants:

David Harvey, AIDS Policy Center, NORA Co-Chair
Miguelina Maldonado, National Minority Action Council, NORA cO-cHAIR
Christine Lubinski, AIDS Action Council
Jane Silver, American Foundation for AIDS Research
Rose Gonzalez, American Nurses' Association
Val Bias, National Hemophilia Foundation
B.J. Harris, National Alliance of State AIDS Directors
Winnie Stackelberg, Human Rights Campaign

NORA members began the meeting by thanking the Administration and the President for their leadership on AIDS issues in the first term, citing funding increases, Presidential leadership , and unprecedented access to the White House and Federal Agencies. They then presented us with a rundown of the current t state of the epidemic and a series of public opinion polls showing support for further action in the areas of AIDS treatment, Vaccine development, Needle Exchange Programs (NEP), and Pediatric drug development.

Specific Points of Interest:

* They strongly encouraged the Administration to lift the ban on use of Federal funds for needle exchange programs. NASTAD mentioned that there are NEPs in 28 states. Podesta asked about the National Governors' Association position on NEPs. While NGA does not have a position

on NEPs the U.S. Conference of Mayors and the National Conference of Black States Legislators are on record in support of NEPs (as well as the AMA, GAO, IOM Committee, American Nurses Association).

* While pleased that the President has requested increased funding for AIDS programs, they believe there is a much greater need. In particular, they mentioned the AIDS Drug Assistance Programs (ADAP) in title II of the Ryan White CARE Act (RWCA).

* NORA would like to see the subject of HIV/AIDS addressed in the public service announcements being developed by ONDCP and NIDA (HHS).

* Pregnant women and children have impaired access to protease inhibitors and many other drugs because they are not approved for use in those groups, nor have there been dosing studies done on pediatric populations.

* They are concerned about the office of National AIDS Policy not having the staffing support needed to play a strong role in orchestrating a national effort to fight the epidemic on all fronts. They also felt the coordinating ability across Agencies in HHS was not supported in the AIDS office at HHS.

* They are unhappy with eh proposed Medicaid per capita cap.

* They continue to support the Adm support of the Office of AIDS Research at NIH

* They want more AIDS expertise in the Domestic Policy Council, the Office of Legislative Affairs and other parts of the White House.