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PRESIDENTIAL ADVISORY COUNCIL ON HIV/AIDS
PROGRESS REPORT

RE-WRITE #6

PREAMBLE
EMBARGOED UNTIL FURTHER NOTICE

In the five years since he assumed office, President Clinton 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 (HOPWA) program has grown by 104 percent. Due in large measure to the Office of AIDS Research (OAR), 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 expedited approval of new drug therapies and of improvements in the medical management of HIV disease, the nation has witnessed the first ever decline in the annual number of AIDS deaths. In addition, the President's AIDS 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 serious action to address the AIDS crisis.

Most of these important strides occurred during the President's first term and under former Office of National AIDS Policy (ONAP) Director Patsy Fleming. Early in his second term, the President, by his appointment of our former colleague from the Presidential Advisory Council on HIV/AIDS (PACHA), Sandra Thurman, as Director of the Office of National AIDS Policy, raised hopes that even greater progress would be made toward 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. We are concerned, however, that the Office of National AIDS Policy has not been provided with adequate staff or appropriate status within the White House structure necessary to make it truly effective.

Despite substantial and diligent efforts on the part of Director Thurman, the ONAP staff and the PACHA Executive Director, progress in the federal response to AIDS has stalled in recent months, contributing to a sense of diminished priority for AIDS issues during the President's second term. When the future of funding for the AIDS Drug Assistance Program (ADAP) was at risk earlier this year, for example, AIDS advocates were forced to look to Congress, not the White House, for leadership. In May, the Vice President announced a 30-day expedited Administration review of the feasibility of expanding Medicaid to cover all indigent HIV-infected individuals; however, many months have passed no pilot project has been put in place and the Administration continues to send mixed and conflicting signals regarding its pursuit of this objective.

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~~ lay out a coherent plan of action. Funding for HIV prevention remains inadequate, particularly when compared with the monumental American bill for medical expenses and lost productivity stemming from HIV disease. With respect to the sparse funding that does flow each year to State and local health departments to support HIV prevention activities, the Centers for Disease Control and Prevention (CDC) has incorporated community planning as a primary implementation strategy but has not fulfilled its oversight responsibility to ensure that States and localities **effectively** target the limited dollars **available** ~~effectively~~. Despite the **scientifically verifiable** ~~fact that~~ the evidence **that** has long existed regarding the efficacy of needle exchange programs, Secretary of Health and Human Services (HHS) ~~Donna Shalala~~ 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 listed below, the Administration has sometimes failed to exhibit the courage **and political will** needed to pursue public health strategies that are politically difficult but 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. On average, HIV-infected individuals in the U.S. are 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 future loss of life. 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 that remain, a renewed dedication to action is essential.

PREVENTION SUBCOMMITTEE

More than 16 years after the epidemic was first recognized, the United States still has not laid out a coherent, effective national strategy to prevent HIV transmission. Experts estimate that 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 counterproductive drug paraphernalia laws. Yet, many years later, our national prevention effort ignores these sound recommendations, ~~and instead of the kind of bold and courageous leadership needed to end the epidemic.~~

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 clear, culturally sensitive language, are ongoing, assist individuals in developing sexual negotiation skills, and are administered by members of the target population.

Perhaps most disturbing is the continued prohibition on federal funding for needle exchange programs despite clear scientific evidence of the efficacy of such programs in preventing new HIV infections without increasing substance use. Fifty percent or more of new HIV infections are traceable to injection drug use. The HHS Secretary has for some time had the legal authority to lift funding restrictions, yet she has failed to do so. The Council applauds the Administration's successful effort earlier this year to preserve the Secretary's authority to waive funding restrictions. However, the Administration has **thus far** expended little effort to educate **Congress and the** American public about the effectiveness of needle exchange programs or to build political support for such programs. The Administration should demonstrate leadership on this issue by **immediately** certifying the public health utility of this life-saving intervention as a component of a continuum of effective HIV prevention services for injection drug users.

Although powerful evidence of the effectiveness of HIV prevention demands a robust and energetic response, the Administration has failed to provide such bold leadership. The federal investment in HIV prevention is disproportionately small compared to the ~~amount of the~~ epidemic's annual price tag in medical care and lost productivity, let alone **in** ~~the~~ human suffering and loss of life.

Moreover, the Administration often **fails to make optimum use** ~~makes poor use~~ of its limited investment in HIV prevention. It has maintained outdated restrictions on the ability of some federally funded HIV prevention programs, especially those targeting school-aged youth, to provide explicit and appropriate information to those at greatest risk. As a result, **many** ~~some~~ HIV prevention educators must censor themselves with an eye to retaining their funding rather than providing the most effective prevention message possible.

Twenty-five percent or more of all new infections occur among individuals under the age of 22. While the CDC is taking steps to **improve and expand its efforts to** target youth at high risk for HIV infection, including gay youth and young women of color, the agency's efforts to educate youth regarding HIV remain uncoordinated and unevaluated. The President's World AIDS Day directive **to all federal agencies to identify programs that offer opportunities to youth for preventing HIV infection** ~~on youth~~ provides a **significant** ~~an~~ opportunity to assess, coordinate, and expand ~~these~~ **Federal** efforts to prevent HIV transmission among America's young people.

We are encouraged by the leadership of Dr. Helene Gayle at the CDC and are impressed by the senior team she has assembled. In particular, we appreciate both Dr. Gayle's involvement of affected communities in the development of HIV prevention strategies and the CDC's continued support of HIV prevention community planning. Unfortunately, the CDC inadequately monitors the public health uses to which federal HIV prevention funds are put by State and local health departments. Consequently, we are concerned **whether** ~~that~~ limited prevention dollars ~~are not most efficiently targeted on those at greatest risk and on support interventions shown to reduce risk behavior~~ **target those at greatest risk and support interventions shown to reduce risk behavior.**

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 and aggressive action on the part of the Administration, the nation stands little chance of **substantially** reducing the number of new infections.

RESEARCH SUBCOMMITTEE

The President is to be highly commended for his leadership in efforts to expedite the work of developing an AIDS vaccine. The President's announcement in May, 1997 of the goal of developing an AIDS vaccine within a decade, and the focus of attention on an AIDS vaccine during the Denver Summit meeting are greatly appreciated and acknowledged worldwide. But much more must be accomplished. Remaining to be addressed are the Council's prior recommendations for: (1) a significant and sustained increase in additional and new funding for AIDS vaccine development; (2) coordinated and comprehensive involvement by all relevant federal agencies in the effort; (3) close federal collaboration with the private sector, international

community, and independent vaccine initiative; and (4) the convening of a public-private AIDS consultative forum.

~~In addition~~, We would like to commend the Food and Drug Administration (FDA) for its efforts in addressing some of the issues we raised concerning women and children infected with or affected by HIV/AIDS. Still lacking, however, are follow-up reports from the FDA on the status of gender accrual analysis by drug sponsors and the status of dissemination of the guidelines regarding participation of pregnant women in clinical trials. The Council also has been concerned about the lack of data on the effects of HIV therapies in children. We appreciate the FDA's efforts in seeing that the labeling process of marketed prescription drugs includes the accumulation and dissemination of pediatric data; however, we are still awaiting our requested review of the number of children actually enrolled in NIH-sponsored clinical trials.

Although it has not been enacted by Congress, the President and Vice President have continued to support the recommendation for a coordinated federal approach for HIV/AIDS research through support for the OAR, including staunch advocacy for a consolidated budget for AIDS research at the NIH.

Demonstrable progress on microbicide research has not been achieved since no new funds have been allocated specifically for this research, no new full-time equivalents (FTEs) have been designated to this effort, no new Requests for Applications (RFAs) have been issued, and no public health consensus panel has been convened to assess the efficacy of available spermicides and other licensed products. TRUE

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 that facilitate rapid translation of these research findings need to be developed.

SERVICES SUBCOMMITTEE

HIV/AIDS requires extensive medical care. Access to such care upon diagnosis is essential and can often result in greatly extending both length and quality of life for those infected. HIV/AIDS medical care also is 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, 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 promising new combination drug therapies, which offer them the best chance for long-term survival. Medicaid, upon which more than 50 percent of people with AIDS rely for health

care, and the Ryan White CARE Act are the existing programs through which most HIV/AIDS care is currently provided.

Since July, 1996, the Council has urged the Administration to begin reviewing existing programs and developing new approaches for providing primary medical care and access to the new drug therapies. In December, 1996, PACHA formally recommended that HHS develop new policies and provide requisite funding to ensure availability of these therapies to all those who need and cannot otherwise afford them, in accordance with HHS recommended treatment 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 ADAP, and only modest increases for primary medical care and other critical support services through the Ryan White CARE Act and HOPWA. Recent reports of a 23 percent decline in AIDS deaths between 1995 and 1996 obscures the corresponding 11 percent increase in the number of people living with AIDS during this same period, many of whom are in critical need of additional services, including the promising new therapies. The Council is looking to the President's FY 99 budget request for a clear indication that the Administration understands both the continuing gravity and urgency of the epidemic and is committed to providing adequate funding support.

2) **Expansion of 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 onset 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 not only a humane policy, but also, we believe, over the long term, a cost-effective strategy as well. Further, unlike ADAP within the Ryan White CARE Act, which covers only drug costs, Medicaid also covers associated primary medical care costs. In addition, since Medicaid is a needs-based entitlement rather than one that is subject to special annual appropriations (as is Ryan White), availability of the new drugs and associated medical services is driven by treatment needs, not by annual appropriations battles.

This past spring, Vice President Gore called for HHS to explore and report to him within 30 days on the feasibility of expanding Medicaid coverage to cover early-intervention HIV therapies. Accordingly, 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 the Health Care Financing Administration (HCFA) has been working closely with the AIDS community and outside policy experts to attempt to develop a viable, cost-effective, ethically appropriate mechanism to provide such expansion. However, we have been deeply disappointed by the apparent absence of personal leadership on this issue from

Secretary Shalala. In a recent meeting attended by Council members, the Secretary suggested the alternative possibility of proposing increased support for ADAP, an option which engenders some skepticism, since it was Congress rather than the Administration that proposed increased ADAP spending in the 1998 federal budget. **Also, the Administration continues to send mixed and conflicting messages of its true intentions regarding this initiative.**

3) **Reduction of the Cost of New Therapies.** The Administration, in conjunction with State AIDS and other public health administrators—and with effective pressure from the advocacy community—has employed, with some success, a number of new ADAP purchasing mechanisms to reduce the cost of the new drug therapies. However, while we recognize the need of drug companies for cost recovery and a reasonable profit, the cost of drugs is still prohibitively high. ~~We urgently need~~ Strong leadership from the Administration on this issue is **urgently needed,** particularly from the Vice President, who has worked with pharmaceutical companies in the past. There are successful examples of "jawboning" private industry on other price issues by other Administrations. Working together with Governors, community advocates, the insurance industry, and the pharmaceutical companies themselves, we believe the Administration can and must help reduce drug prices.

4) **Monitoring of Access to 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 Alexis Herman and **Donna** Shalala and members of the Commission for this sensitivity and look forward to working with them to ensure implementation of these recommendations.

5) **A National Policy Dialogue on How to Provide Comprehensive HIV Care.** 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. Currently, **Medicaid,** the Ryan White CARE Act, ~~Medicaid~~, and other ancillary funding sources are providing critically needed support for sustaining a comprehensive continuum of HIV care. However, the impact of new drug therapies on the clinical course of ~~HIV disease~~ and potential new manifestations of HIV disease must inevitably result in modification of the existing provision of services and will require additional funding. Despite significant efforts to promote a formal, structured, national policy dialogue, progress has stalled. At the same time, the changing nature of the epidemic has sparked a new sense of urgency for such dialogue, which, in **many** ~~some~~ cases, has already begun at the local level. A comprehensive review of HIV service delivery and funding mechanisms at the federal, State, and

community levels must be undertaken at the earliest possible date, with active participation by all affected parties.

[6) **Indian Health Service.** We are greatly concerned that the Indian Health Service (IHS) still has not developed adequate HIV/AIDS prevention and treatment programs or ongoing communications with Native American organizations in the AIDS health care arena. Rural services, in particular, continue to have staffing and access problems. The IHS also has not provided updated case management guidelines that ensure cultural sensitivity and access to traditional treatments.]

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 2½ years ago, the Council raised this issue and the President responded in a supportive manner.

Since then, the Job Corps has revised its policy from requiring special mandatory testing to routine testing for HIV as part of its entry process. It retains more than 80 percent of those who test HIV-positive and provides requisite counseling and care, ~~for them~~, regardless of whether **HIV-positive applicants** ~~they~~ are subsequently accepted as students. This exemplary policy by the Job Corps should be commended.

The Department of Defense (DOD) maintains stringent standards for appointment, enlistment, or induction into military service. The DOD does not discharge individuals testing HIV-positive after appointment, enlistment, or induction solely on the basis of a positive test. Periodic medical evaluation of fitness for continued service of HIV-positive personnel is conducted in the same manner as for personnel with other progressive illnesses. Evidence of HIV infection may not be used as a basis for any disciplinary action and HIV-positive personnel are assigned within the U.S. in order to ensure access to appropriate medical care. The DOD policies regarding HIV-infected individuals appear to be comparable to those for other medical disqualifications. Its policies regarding those subsequently infected are exemplary and should be commended.

The U.S. Foreign Service requires mandatory HIV testing, and those found to be HIV-positive are disqualified from entry (subject to a possible waiver, which is seldom granted) because of the resulting limitations on "worldwide availability" **for placement**. Foreign Service employees who become HIV-positive subsequent to entry are issued limited medical clearances and may serve in countries where adequate medical care is available. In both cases, treatment of HIV-infected individuals appears to be comparable to treatment of those with similarly serious medical conditions.

The Peace Corps requires HIV testing as part of a comprehensive pre-entry medical assessment. HIV is listed as a condition that, with rare exception, the Peace Corps is unwilling to reasonably accommodate. It further provides for deferred entry with certain conditions after a specific time period. Advances in HIV therapy and resulting improvements in general health and quality of life for HIV-infected individuals may require future recatagorization to deferred entry status after meeting certain conditions for a specified time period.

After much debate and discussion, the CDC finally has scheduled a working group meeting of external experts for February 12, 1998 to review CDC Guidelines for preventing HIV transmission from infected health care workers during exposure-prone procedures. It is our sincere hope that this will lead to prompt revision of its current discredited and discriminatory guidelines.

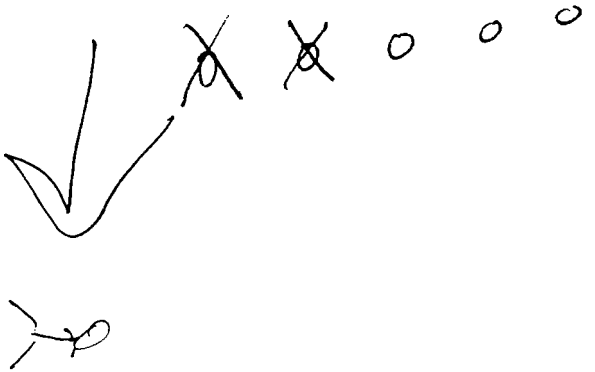
PRISONS SUBCOMMITTEE

Since 1990, HIV/AIDS has been the second leading cause of death in prisons. The incidence of AIDS in prisons is six times greater than 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 he/she returns. 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 nation's 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 by the Council. A number of concerns outlined in our 1996 report have not been addressed, and many appropriate recommendations from the National Commission on AIDS have not 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 ensuring 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 **other alternatives for compassionate release, consistant with the standards adopted by** the American Bar Association (ABA), ~~standards for compassionate release~~ should be reexamined as an alternative to the current Federal Bureau of Prisons guidelines.

During incarceration, inmates **should** ~~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 **also** have access to compassionate-use therapies that have proven efficacious but have not been FDA-approved.

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 inmate 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** ~~that~~ 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 shortsighted. Also, ~~we are not persuaded by the~~ **the scientific literature does not support the Bureau of Prisons** concern that access to protective barriers would "create an environment in which control would be difficult." ~~(BoP Conference Call 10/14/97)~~. The documented transmission of sexually transmitted diseases (STDs) in prisons 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 are concerned that HIV in correctional settings may not be receiving the attention it deserves.~~ ~~We~~ **The Council** remains 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

Recent data has confirmed our fears that the global HIV/AIDS epidemic is, in fact, worse than had been predicted. Important as the new developments in therapy are in reducing the suffering and prolonging the lives of people living with HIV/AIDS in the few countries where treatment is possible and affordable, ~~nothing~~ **too little** is being done to halt the relentless march of this disease in Africa, Asia, Latin America, and Eastern Europe. Thus, the President's ~~extraordinary~~ leadership in setting ~~the~~ **as a** goal ~~for~~ the development of an AIDS vaccine in the next ten years merits sincere praise.

The inclusion of HIV/AIDS on the agendas of bilateral and multilateral meetings, such as occurred at the Denver Summit, also represents a significant achievement by the Administration.

The Administration also deserves credit for ensuring the prompt filling of vacancies in the United States Agency for International Development (USAID) with individuals expert in the subject of HIV/AIDS. The dialogue between USAID and nongovernmental organizations is to be commended.

The global HIV/AIDS crisis, however, constitutes a direct threat to the economic and strategic interests of the United States. In light of the ever-worsening global epidemic, PACHA is disappointed that the Department of State has not conducted 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~~ **as** a 2-year plan. It must be thoroughly assessed, and a current international strategy should be developed promptly with input from domestic and international organizations involved in the response to the global pandemic.

Until a vaccine is globally available, the United States must consistently and affirmatively reestablish its commitment to lead a worldwide effort to reduce the rate of new infections. Such leadership must include the direct involvement of Secretary of State Madeline Albright, as well as increased funding of global AIDS programs in the U.S. agencies and U.S.-supported international organizations. The lofty objectives contained in the International Section of the National AIDS Strategy must be pursued and achieved in a vigorous and coordinated U.S. government effort—before it is too late to make a difference in the social, economic, and political **impacts** ~~effects~~ of the pandemic.

PRESIDENTIAL

ADVISORY

COUNCIL ON

HIV/AIDS

December 5, 1997

MEMORANDUM TO SANDRA L. THURMAN AND TODD SUMMERS

FROM: R. Scott Hitt, M.D., Chair

RE: Draft Progress Report of the Council - Re-Write #6

FAX: (202) 245-9835

Attached is Re-Write #6 of the Progress Report. This should be nearly final having been vetted by each subcommittee and individual Council members. The most recent changes are in bold for additions and strike-throughs for deletions.

The Council has strived to maintain a factual, balanced, and respectful, but firm assessment of the Administration and its response to our recommendations. While on many levels there has been tremendous progress by this Administration, there are many issues that are still of great concern to this Council.

We appreciate your feedback on earlier versions of this document and ask that you provide any further feedback to me as soon as possible. The Council is committed to working within the Administration. In order to address our concerns, we ask that you seriously consider the following requests:

- Private meeting by the two of us with the President to discuss the Council's concerns and frustrations;
- A commitment by the President to hold a meeting with the Council at our next Council meeting March 15-18, 1998 (last formal meeting with the Council was in July 1995; also many new members have been added since that meeting);
- A commitment by the Administration to immediately address the inadequate staffing of the Office of National AIDS Policy and the lack of appropriate status within the White House structure necessary to make it truly effective;
- A commitment by the Administration to move forward on a comprehensive strategy for early intervention services and treatment (especially in light of today's article in the Washington Post "Administration Drops Effort to Extend Medicaid Coverage for AIDS Therapies" and the message received from our most recent meeting

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Washington, DC 20006

- with HCFA (PACHA Services Subcommittee, Thursday, December 4 where we were told Medicaid Expansion was still actively being reviewed and no mention was made regarding abandonment of this effort); and
- A commitment by the Administration to immediately name a policy team to develop a comprehensive strategy for early intervention services and treatment.

We look forward to a productive collaboration with the Administration.

PRESIDENTIAL ADVISORY COUNCIL ON HIV/AIDS

EXECUTIVE SUMMARIES

RE-WRITE #4

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 __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 the medical management of HIV disease, the nation has witnessed the first ever decline in the annual number of AIDS deaths. In addition, the President's HIV 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 national 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~~ issues, 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 a 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~~. no strategy

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 inadequate

not fulfilled

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 **listed below** ~~that are politically tough but scientifically sound~~, the Administration has ~~often~~ **sometimes** failed to exhibit the courage needed to pursue public health strategies that **are politically difficult but** 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 ~~still lacks a~~ coherent, effective national strategy to prevent HIV transmission. Experts estimate more than

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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.

Perhaps most ~~dismaying~~ disturbing is the continued prohibition on federal funding for needle exchange programs **despite clear scientific evidence of the efficacy of such programs in preventing new HIV infections without increasing substance use**. Fifty percent or more of new HIV infections are traceable to **injection drug** ~~substance~~ use. The Secretary has for **some time** had the legal authority to lift funding restrictions with a stroke of the pen, yet she has failed to do so. Moreover, the ~~Secretary~~ **Administration has** expended little effort to educate the American public about the **effectiveness of** needle exchange **programs** 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~~ **on** needle exchange **currently exist, the President should demonstrate leadership** ~~nonetheless show leadership~~ on this issue by immediately certifying the public health utility of this life saving intervention **in announcing plans to lift the funding restrictions immediately upon expiration of the moratorium. 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.**

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.

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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 **and aggressive action** on the part of the Administration, the nation stands little chance of reducing the epidemic's burden in future years.

RESEARCH SUBCOMMITTEE

Denver "G-8"

The President's is to be highly commended for his leadership in efforts to ~~begin~~ **expedite** the work of developing an AIDS vaccine. The President's announcement **in May 1997** of the goal of **developing** an AIDS vaccine within a decade ~~in May, 1997,~~ and the focus **of attention** 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 **additional and new** funding for AIDS vaccine development, (2) a coordinated and comprehensive involvement by all relevant Federal agencies in the effort, (3) close **Federal** collaboration with the private sector, international community and independent vaccine initiative and (4) the convening under the Vice-President's auspices of a public-private AIDS consultative forum.)

The Food and Drug Administration (FDA) is to be commended for its efforts to address **certain gender issues** ~~some of the issues surrounding gender~~ as recommended by the Council. **In addition, we would like to commend the Food and Drug Administration for its efforts in addressing some of the issues we raised concerning women and children infected with or affected by HIV/AIDS.** ~~The Council still needs a~~ **Still lacking, however, are 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.

reflects clinical

Although not yet enacted by Congress, 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. Also,~~ **Insufficient progress on microbicide research has not been achieved since** 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~~ **and no** public health consensus panel to assess the efficacy of available spermicides and other licensed products has ~~not yet~~ 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, upon which over 50 % of people with AIDS rely for health,

Since July, 1996, the ~~Committee~~ **Council** 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~~ **In** December, 1996, Council ~~recommendations~~, **recommended that HHS develop** ~~to take those steps necessary to ensure that~~ new policies **and provide requisite funding to ensure availability of these** ~~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:

and cannot otherwise afford

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 99 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 **as well.** ~~based on the possible delay or reduction of expensive hospital and other costs associated with disease progression~~. ~~Also~~, **Additionally**, 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 **also** 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. **Accordingly,** 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 since 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.

Mike talk to Bob write it

PRESIDENTIAL ADVISORY COUNCIL ON HIV/AIDS
EXECUTIVE SUMMARIES

RE-WRITE #3

PREAMBLE

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 __ percent, spending on AIDS research has grown by __%, HIV prevention funding has increased by __%, and federal support for the Housing Opportunities for People With AIDS program has grown by __%. 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

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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.

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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.

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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.)

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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.

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not moving at pace it needs to
be prioritized

"arrogant evasion" - foreign service

Talking Points for Dr. Scott Hitt

Update of Interim Activities

- **Welcome**

- **Introduction of Council Members**

- **Acknowledge that the meeting is open to the public and that tape recorders are being used.**

- **Acknowledge that structured public comment time has been built into the agenda, and that anyone who wishes to speak should sign in with at the registration desk.**

  Encourage individuals to provide written comment(s) to the Council for their consideration.

- **Thank You's/Acknowledgments**

  -- To the Council Members for all their continued work, especially since the last meeting

  -- To each of the individuals who have agreed to come and make presentations to the Council over the next several days. It is their expertise and experience which helps lead the Council in making sound, reality based recommendations to the Administration, and it is there work which serves to guide us in our efforts. Council members are not experts in every issue, and we understand the value of input from those who are in the field everyday.

  -- To Social and Scientific Systems staff who have worked so hard to coordinate this meeting.

  - To those individuals in the agencies who work so hard to implement the policies that the Administration and Congress set, and to respond to our concerns.

  -- To ONAP staff who have worked so hard to ensure that the Council has the information it needs to have full discussion of the issues., including Sandy Thurman, Todd Summers, Paul Yandura, Jeff Kamen, and Sarah Howelinski.

  -- I would also like to welcome two new agency representatives to ONAP:

  Bob Solis, who is an agency representative from the Health Resources and Services Administration; and

Matthew Murguia, who is an agency representative from the Office of Minority Health in the Office of the Secretary at Health and Human Services.

-- I would also like to acknowledge the work that both Glenda Simmons and Anil Soni, two interns who will be leaving ONAP shortly to return to their studies

-- Finally, I want to say a special thank you to all of you in the AIDS community, including those who are here today to provide public or written comments, who, day in and day out, give of yourself in a tireless and selfless way so that others can have a better life.

-- I also apologize if there is anyone I left out, but often the un-thanked individual whose contributions are most noticed.

- **Discussion of Interim Activities**

-- General Overview of Legislative/Appropriations Successes
(which will be covered in detail during Sandy Thurman's comments and a subsequent presentation by NORA in the Services sub-committee meeting later this afternoon)

In general, we are very pleased by the increases in funding which have occurred over the last legislative session: For example

Ryan White Funding increased by percent
HOPWA Funding increased by percent
Prevention Funding at CDC increased by percent

This Council is pleased that the Secretary maintains her authority regarding needle exchange although we are concerned about the moratorium on any action which was adopted by Congress.

-- World AIDS Day Activities

Acknowledge efforts of all four principles: President's Video, Mrs. Clinton's appearance, Mr. and Mrs. Gore's meeting with Children and the efforts by different agencies (attached).

Thank all of those communities which commemorated World AIDS Day at the local level. Acknowledge that it will continue to be the grass roots movement which will make the most progress in addressing AIDS.

This year's theme of "Give Children Hope in a World with AIDS" is very poignant given recent statistics which show that some 25% of all new infections are occurring in young people.

- **Discussion/Review of the Role and Responsibility of the Council**

-- Change the discussion somewhat to talk about the Advisory Council and what our role and responsibility are to both the President and to the public at large:

-- the President stated very clearly when he address the first meeting of the Council on what he believed the function of the Council should be:

Provide **ADVICE, INFORMATION AND RECOMMENDATIONS** regarding **PROGRAMS** and **POLICIES** and programs intended to promote effective prevention of HIV disease; advance research on HIV and AIDS, and promote quality services to persons living with HIV disease and AIDS.

The Executive Order states clearly that the purpose of the Council shall be "**SOLELY ADVISORY IN NATURE**"

-- the functions of the Council are also laid out in the Federal Advisory Committee Act and other Federal legislation, **which limits our ability to lobby for specific legislation and prohibits us from lobbying members of Congress while we are attending this meeting.**

-- I also want to discussion what I see as my role as the Chair

Provides leadership and direction of the Council
Help maintain focus of efforts
Help, along with each of your, to place a reality check on our efforts and recommendations. (It does no good to make recommendations which have no chance of implementation and could serve possibly to only damage our credibility.)

That does NOT mean we do not push the envelope, but we must do it in a responsible manner.

-- Role of the Federal Representative to the Council (Daniel Montoya)

Also need to acknowledge the role of the Federal Representative on the Council, Daniel Montoya and thank him for all the work he does in support of the Advisory Council.

By law, his role is as follows:

-- Officially calls meetings
-- Provides for maintenance of records
-- En sure all laws, rules and regulations regarding advisory committees are followed
-- He may, upon his determination, end a meeting if he believes it is in the best interest of the government to do so

Daniel has also taken on the role of providing staff support for the Council, and we are eternally grateful to him for that.

However, we must remember that he provides support; this does not mean he is our employee.

The same must be said for ONAP:

ONAP has a role that is different from that of the Advisory Council. ONAP's role is to focus the efforts of the Federal government into a unified response to AIDS, coordinating policy and programmatic activities as necessary.

The distinction is that the Advisory Council provides advice to the President and that ONAP is responsible to the President. While there is a lot of overlap, the Advisory Council and ONAP are not the same, and they may not always agree.

-- Overview of What Makes a Good Advisory Council Member

Finally, I want to just mention a few things that make for a good advisory council member, myself included.

I do this only as a means to help us stay focused and effective. There are so many issues we could and should be involved in, and rightfully so.

However, we must pick and choose our issues carefully so that we do not overwhelm ourselves nor do we lose our ability to provide sound advice by being to entangled into details rather than the big picture.

We must remember that we cannot, no matter how much we may want to,micro manage the Federal government and its activities.

Clearly, we need to focus on areas of concern which are most important to people living with HIV, (and in prevention new infections).

(We must also have confidence in those within the Federal government to do the right thing -- always maintaining our vigilance to point our areas for improvement.)

- **Review of Agenda**

-- Many Issues to Cover over the next few days. As in the past, much of this work will be done in subcommittees and via presentations by outside efforts.

Over the next four days, we will cover such topics as:

Progress Report Update
Vaccine Development Progress
FY 1988 Appropriations
Youth Issues
Managed Care
Consumer Protection and Quality in the Health Care Industry
Medicaid Expansion and Medicaid Waivers
The AIDS Drug Assistance Program
Discussion of a National Policy Dialogue
Substance Abuse Treatment and Prevention Issues
HIV Surveillance Issues

-- Urge the Council to stay focused on the agenda at hand for the next few days; avoid tangents, and to remember our charge is provide advice and recommendations. Thus, all our discussions should focus on that as the immediate goal.

-- Acknowledge that the Council cannot, nor would it be appropriate for them to attempt to cover every issue at every meeting, nor should we try to do so.

-- Rather, the Council at this meeting is focusing on developing a progress review, or assessment, of the Administration's response to previous recommendations. I will discuss this in more detail when we get to the Progress Review section of the agenda.

NOW, WE HAVE A LONG FOUR DAYS AHEAD OF US, SO LET'S GET TO WORK.

N:\COUNCIL\DECMTG.97\TALKPOIN.RSH

EXECUTIVE OFFICE OF THE PRESIDENT
OFFICE OF MANAGEMENT AND BUDGET

Route Slip

FAXED TO: JOSH GOTBAUM	Take necessary action	
LARRY HAAS	Approval or signature	
TODD SUMMERS	Comment	
RICHARD TURMAN	Prepare reply	
	Discuss with me	
	For your information	
	See remarks below	
From: Steve Mertens	Date: December 5,1997	

Remarks:

Attached, for your information, is a response from the Department of Justice's Bureau of Prisons regarding the draft recommendations of the Prisons Subcommittee of the President's Advisory Council on HIV and AIDS which we shared with them yesterday.

If you have any questions or need additional information, please let me know (395-4935).

Attachment

U.S. Department of Justice

Federal Bureau of Prisons

Washington, DC 20534

December 4, 1997

MEMORANDUM FOR ROBIN BEUSSE, ADMINISTRATION DIVISION

FROM: David Good, Chief, Health Programs Branch
National Health Systems Administrator

SUBJECT: Response to OMB Request for BOP Comment

This is in response to your request for our review of the documentation supplied to OMB from the President's Advisory Council on HIV & AIDS, Prisons Subcommittee. Health Services Division has had extensive contact with the President's Advisory Council on HIV & AIDS, Prisons Subcommittee, for the past two and one-half years. The Prisons Subcommittee has been critical of the Bureau's policy prohibiting inmates access to drug paraphernalia and sexual activity items such as condoms and dental dams.

The Prisons Subcommittee insists the only way to adequately protect inmates from themselves is to provide them with clean needles so they can inject illegal drugs, and to provide them condoms/dental dams so they can participate in prohibited sexual activity in prison. Their argument is that inmates will participate in this activity anyway, so we should provide them with these items so they do not contract HIV.

The Bureau strongly disagrees with the Prisons Subcommittee philosophy. The Bureau provides inmates and staff with extensive HIV/infectious disease education on transmission and prevention of infectious diseases in a correctional environment. Inmates who engage in high risk behavior such as I.V. drug abuse and sexual activity are removed from the inmate general population and appropriate sanctions are placed on these inmates. Additionally, these inmates are then monitored to prevent further similar activity. What the Prisons Subcommittee fails to recognize, accept, or even discuss, is the fact that these inmates are participating in prohibited behavior within a correctional institution. Correctional environments are not the same as rural, suburban, or metropolitan areas. Security is the main concern within correctional environments. The Federal Bureau of Prisons (BOP) has extensive experience in dealing with illegal inmate drug abuse and prohibited inmate sexual activity. Both of these activities can result in institution security breaches, staff corruption and inmate violence. The Prisons Subcommittee cites several correctional environments that permit needle exchange for illegal drug use and condoms for

prohibited inmate sexual activity, stating that there is no increase in violence nor security breaches in these correctional systems. We find this argument unsubstantiated and not thoroughly researched. The BOP will not permit these items in the correctional environment.

Responding to the actual language under the heading "Prisons Subcommittee", we offer the following comments:

- Paragraph 1, no discrepancies.

- Paragraph 2, the Prisons Subcommittee states "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." Response: As stated above, we disagree with their assessment that unless we provide condoms and drug paraphanalia, that inmates are at risk. The BOP provides not only extensive education on the prevention and transmission of infectious diseases to the inmates, we provide all FDA approved drugs to appropriately evaluated inmates.

- Paragraph 3, the Prisons Subcommittee states "we continue to believe that the ABA standards for Compassionate Release should be re-examined as an alternative to the current Federal Bureau of Prisons guidelines." Response: The BOP does not agree with the ABA standards for Compassionate Release which essentially would release all HIV positive inmates. Medical Compassionate Release is reserved for those inmates with terminal illnesses, usually with a definiinitive life expectancy.

- Paragraph 4, the Prisons Subcommittee states "Federal prisoners should have access to compassionate use therapies which are proven efficacious, but not yet FDA approved." Response: The BOP concurs with this approach to treatment, however, with reservations. Inmates must not be used as experimental objects. The BOP already authorizes on an case by case basis experimental HIV treatment modalities not yet approved by the FDA but approved by the FDA as experimental treatment modalities.

- Paragraph 5, Response: The BOP does provide appropriate substance abuse programs to all eligible inmates. The Prison Sub-committee states "discussions should continue on inmates' access to clean substance use paraphernalia" The BOP is not continuing any discussion with any group on inmate's access to illegal drug abuse paraphernalia.

- Paragraph 6, as discussed previously, condoms/dental dams are not an option in the BOP due to the security risks and concerns. The comment from the Prisons Subcommittee that "our approach is short-sighted" is an uninformed opinion made by non-correctional individuals. These individuals have no experience nor expertise in correctional management.

- Paragraph 7, Response: The BOP provides appropriate infectious disease treatment to all BOP inmates. These therapies are properly evaluated and administered to inmates who can tolerate the treatments and where the best result can be obtained for the inmates. The BOP puts HIV and other infectious diseases as its highest medical priority. This has been the case for the past few

years. The Prisons Subcommittee does not understand and rejects all correctional necessities in favor of provding HIV positive inmates all treatments, all prevention measures such as illegal drug paraphernalia and condoms, without regard for the safety of other inmates, staff, and the community surrounding the institution. The BOP has an obligation to provide inmates a safe and humane incarceration environment as well as balancing the security of the Federal Prisons System. We believe we have this obligation in balance. Some of the recommendations from the Prisons Subcommittee could place the BOP, inmates, and the community at risk.

If I can offer any further information on this matter, please contact me at (202) 307-2867, ext. 106.

Presidential Advisory Council on HIV/AIDS
Executive Summaries

Prevention Subcommittee

More than 16 years after the epidemic was first recognized and five years into an administration that promised leadership in the effort to "reduce the number of new infections until there are none," the United States sill lacks a coherent, effective national strategy to prevent HIV transmission. The results are appallingly predictable. More than 40,000 Americans become infected with HIV each year. 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.

During the early years of the epidemic, former Surgeon General C. Everett Koop and eminent organizations, such as the Institutes of Medicine and the Presidential Commission on AIDS, 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.

Subsequent research has confirmed the validity of these recommended strategies. 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 to address sexual behavior are most effective when they provide explicit information, 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. One widely-cited study by leading researchers, for example, determined that needle exchange reduced HIV infection rates by 50 percent or more.

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. While the societal costs of AIDS have grown exponentially, HIV prevention has declined as a percentage of government AIDS-related spending.

Worse still, the Administration makes exceedingly poor use of its paltry investment in HIV prevention. The Administration has maintained outdated and reactionary restrictions on the ability of federally-funded HIV prevention programs to provide explicit information to those at greatest risk, encouraging HIV prevention educators to censor themselves in order to retain their federal funding. Moreover, rather than ensure that scarce prevention funds actually go to those in greatest need, the Centers for Disease Control and Prevention barely monitors the uses to which federal HIV prevention funds are put by state and local health departments.

The Administration's timidity in the face of this frightening health emergency is most powerfully exemplified by the continued prohibition on federal funding for needle exchange programs. The President could lift these funding restrictions with a stroke of the pen, yet he has failed to do so. Even though 50 percent or more of new HIV infections are traceable to substance use, the Administration appears inexcusably and inexplicably unwilling to respond to this worsening crisis.

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 half-hearted, 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, the Administration has no plan for achieving this lofty 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 leadership is to be highly commended for his efforts to begin the work of developing an AIDS vaccine. The President's announcement of the goal of an AIDS vaccine within the decade in May, 1997, and the focus on an AIDS vaccine during the G-7 meeting is unsurpassed and 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 while not completely accomplished are being reviewed and addressed. The Council is committed to continuing the work that has begun and will be submitting additional recommendations during our December, 1997, meeting in order to reach the goal of an AIDS vaccine.

The Food and Drug Administration (FDA) is to be commended for their efforts to address some of the gender issues 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 drugs on children. Again the FDA has acted on this issue and is to be commended for it's efforts to see that labeling of marketed prescription drugs includes pediatric data. However, another recommendation calling for an on-going review of the numbers of children actually enrolled in NIH sponsored clinical trials has not been addressed or implemented.

What do they mean?

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 yet to be achieved.

OK

While some work on microbicides has been accomplished, the three recommendations on microbicide research, approved by the Council in December, 1995, have not been fully addressed. No new funds have been allocated for microbicide research, no new full-time equivalents (FTEs) have been designated to the effort, no new Requests for Applications (RFAs) have been issued which might interest new investigators in the field, and a public health consensus panel to assess the efficacy of available spermicides and other licensed products has not been convened.

?

(100×10^6 was promised by Sen., over a 4 year period @ UNAIDS

The recommendation for ongoing mechanisms to ensure the rapid translation of breakthrough research findings into clinical practice has been addressed by NIH in the areas of the biomedical research findings. NIH has several mechanisms in place that provide rapid dissemination of these findings. In the area of behavioral and social science, mechanisms need to be developed that also provide rapid translation/dissemination of research findings. It is the Council's intent to address this issue in future recommendations.

Since the work of the Council began in July, 1995, the Research Committee has made 17 recommendations, approved by the full Council, addressing some of the issues on the above topics. Several of these recommendations have been acted upon with vigor, with resultant resolution of the problem being addressed. Other recommendations are currently being reviewed or addressed, while others have been largely ignored.

~5 Centers NATIONally

Center for AIDS Prevention Studies (CAPS)

~~Expressed~~ goal is to disseminate behavioral & social science research that has proven efficacy.

In addition to multiple meetings they have a web site & an ongoing mailing of Newsletter that reviews the recently published literature by high risk group.

Eg: Prison and
- Adolescents
- Adolescent Gay →
- ♀
- Gay men of color

& Heterosexual Black, Hisp Asian NA Pacific Islander

Services Subcommittee

The following issues constitute major current priorities for the Services Committee:

1) Access to the new therapies.

A year ago, and following promising trials with the new combinations therapies, HHS undertook to develop new HIV treatment guidelines. Because early intervention appeared at the time to be a likely recommendation, the committee and the full Council urged that the Administration announce simultaneously with the new guidelines a strategy for providing insurance coverage (or other means) to ensure that all those who could benefit medically from the new therapies would have financial access to them. We saw this primarily as a humane approach, but because of avoided costs associated with disease progression, and even a return to work and taxpayer status for many, we saw it as a potential cost-benefit as well. A new strategy for access is especially important for Medicaid, the largest payor for HIV/AIDS medical services, because people with HIV are precluded from Medicaid coverage for early intervention because only disease progression triggers the disability determination which in turn triggers Medicaid coverage. What was previously seen as a benign policy becomes, in light of the new treatments, perverse. ← Why? — How about any other disease for which we develop guidelines but do not necessarily pay for it

We were heartened by the Vice President's call for an exploration of the feasibility of expanding Medicaid coverage to provide access to the new therapies, but stunned to hear from the Secretary of HHS in a recent meeting that she had taken this idea "off the table." Moreover, she has offered only a vague assurance that the same end could be assured through an increased appropriation in the AIDS Drug Assistance Program (ADAP). We do not have at this time from HHS a reliable cost estimate for such expansion of ADAP, nor a political strategy. If we are intensely interested in this turn of events, perhaps it is related to the fact that it was the Congress, not the Administration, that proposed increased ADAP funding in the 1997-98 federal budget.

This flailing about, without apparent commitment, and certainly without a plan for access, is causing unnecessary human suffering, and hastening death, for many people with HIV/AIDS, and must be addressed at once.

2) National policy dialogue.

Nearly a year ago, again in light of the new therapies, the Committee and the council called for a national dialogue on how the federal government structures and pays for medical and support services for people with HIV/AIDS. The Ryan White CARE Act has been a major vehicle for this purpose, but it has been structured to address a disease that proceeds to death at a relatively rapid rate. With the new therapies, and the possibility of deferring symptomatic episodes, and perhaps for

In actual fact our entire effort has been focused for 3-4 years on ... individuals entered in care services. Indeed, this is the predominate ... in AIDS death rate

HHS to have focused meeting on this specific issue in Feb-March.

many, turning HIV/AIDS into a chronic disease, the fundamental assumptions of Ryan White and other federal policies ~~bear re-examination.~~

Each Agency is dealing with this now

With support from the Vice President's office and the Office of National AIDS Policy, a national policy dialogue process was developed by the prestigious Keystone Center. This process has now been blocked by HHS, with no alternative process proposed. In the absence of such a process and as the epidemic and new therapies evolve, Ryan White and other federal programs may be increasingly ill-suited to meeting the critical medical and social service needs of people with HIV/AIDS. This will unnecessarily invite criticism from AIDS advocates, and even the Congress, of programs that have been generally effective, but that need to be restructured to continue their effectiveness.

Since Jan, 1995

~~Right~~ white, rich-man perspective

HHS Internal Dialogue Efficacy of Fed Programs
- CDC/NIH/HRSA/SAMHSA/AHCPR/FDA
- convened by OHAP
- culminates in meeting Feb. March.

Once completed → external dialogue with community interest groups

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 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.

Not true

3

CDC/others

Scheduled to occur. Early '98

Prisons Subcommittee

The Committee on Prison Issues has examined a number of issues. Among these are compassionate release programs, educational programs, protective barriers and harm reduction, standards of care and implementation of the recommendations of the National Commission on AIDS (which the Department of Justice states it has not had the opportunity to review - memo, 5/9/97). In general, the responses we have received from representatives of the Federal Bureau of Prisons have been neither prompt nor direct generating great concern over a number of issues involving HIV/AIDS in Correctional settings. Among the more noteworthy are the following:

1. Compassionate Release.

Compassionate release for severely infected individuals is reasonable and humane, yet this option is rarely considered in federal prisons. (DoJ states that revisions are not necessary - memos, 7/8/97 & 10/15/97). The appropriate codes must be reviewed and revised in order to make this option more available to terminally ill inmates who do not pose a threat to society.

2. Protective Barriers.

Federal officials are simply unwilling to discuss the use of protective barriers for prisoners (stating this is inappropriate for inmates; "condoms and/or dental dams are not medically necessary..." - memo, 7/8/97 & 10/15/97). Another argument against protective barriers is that such devised would create an "environment in which control would be difficult." What we do know from the most recent reported data of the CDC & DoJ is that in many Correctional settings the incidence of STD's is high. Prisoners are having sex. We feel it is imperative that we address the reality and attempt to curb not only the spread of HIV but also Hepatitis and other STD's. Successful models for condom distribution are in place in several facilities are worth examining/piloting in federal facilities.

3. Substance Use.

In the context of more comprehensive Harm Reduction approach to HIV management, resources for substance use treatment are essential yet not easily accessible in federal prisons ("inmates who volunteer for treatment "are admitted into residential substance abuse programs in sequential order based upon release date - memo, 10/15/97). Review of waiting periods and program content should be conducted and necessary program expansion planned in order to accommodate inmates within a reasonable time period.

HIV Disease has demanded a reevaluation of the ways in which we have traditionally approached prevention, education, psychosocial/medical intervention, and treatment. While the Federal Bureau of Prisons has developed policies and procedures for dealing with many HIV issues, testimony from those who are or who

have been incarcerated reveal an intransigence at the level at which these policies are carried out. Access and treatment for chemical dependency, varies widely. Case management with appropriate referral and follow-up upon release is inconsistent. Model programs have been funded in select sites and are worthy of examination and expansion into other facilities. The Subcommittee on Prison Issues expresses concern that HIV in Correctional settings may not be being addressed from a public health perspective. The lack of investment in HIV prevention and care while individuals are incarcerated is a significant barrier against reducing the spread of HIV within Correctional settings and into the general population.

Agree this needs to be better coordinated with HHS related programs at the State & Local levels.

OHAP c̄ CDC/HRSA have begun a dialogue c̄ DOJ resulting in

A. Review of medical standards of care {HIV STD TB recently released by DOJ/Fed Prisons medical director (Ken Montague)

~~B.~~

B. DOJ will ask HHS for assistance Sec → Att General → Montague

International Subcommittee

The Presidential Advisory Council is quite 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. Thus, it should have been thoroughly assessed, and a current international strategy should have been promptly developed.

Given the ever-growing and ever-worsening global pandemic, the failure of the Department of State to assume a leadership role within the U.S. government and the global community is inexcusable and unconscionable.

Additionally, insofar as the United States Agency for International Development constitutes the primary U.S. effort to respond to the international AIDS' crisis, the failure of the President to seek increased appropriations for USAID from Congress does not make any sense to the Council. true? yr

We emphatically urge 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. We request that the State Department report on its assessment of its 1995 International Strategy on HIV/AIDS and the status of the development of a current strategy.

The Advisory Council considers the depth and breadth of the global AIDS crisis to constitute a direct threat to the economic and strategic interests of the United States, and thus requires a commensurate level of action by the United States government.

Sandy has begun a dialogue w/ all principals at USAID; WHO; HHS; and multiple NGO's. If this is a high priority of POTUS it is in direct conflict w/ resource allocation, and a prioritization needs to be forthcoming.

NO mention of Sandy's efforts

Presidential Advisory Council on HIV/AIDS

Proposed Recommendations
for Adoption at the December 1997 Meeting

Discrimination Subcommittee:

The Administration should work with Congress to create stronger protections for medical privacy, and should revise its legislative proposals on the subject to permit law enforcement authorities access to patient records only after they have obtained a warrant or meaningful and informed patient consent.

Prevention Subcommittee:

I. The President shall instruct the Secretary to develop oversight guidelines within 60 days of the re-evaluation of Model Paraphanalia and Prescription code directed towards the lifting of the federal ban on Needle Exchange in 120 days.

II. In recognition of the inadequacy of the current HIV surveillance system and the need to have better information about current HIV infections a quickly as possible, the Council urges the President to initiate a study through the CDC of the methodologies and efficacy of various HIV reporting mechanisms, including, but not limited to, random sampling and unique identifier systems. We also urge the President to convene a National Surveillance Meeting including, at a minimum, the CDC, HRSA, HCFA, the Department of Justice, and state representatives where non-named reporting occurs to address in a holistic way the implications of moving to nationwide HIV reporting and to oppose the apparent federal trend towards quick implementation of name-based HIV reporting. The meeting agenda should include review of the full range of reporting mechanisms, incentives and disincentives to HIV testing in each system, identification and assessment of built-in gaps and biases, liabilities and benefits to individuals and to public health, goals and objectives of HIV reporting, and links to preserving concurrent anonymous testing programs.

Background to this resolution: HIV reporting, in and of itself, does not fill the significant gaps that exist in understanding the spread of HIV. In the absence of federally assured medical services whose goal is getting people into early, aggressive treatment (inclusive of necessarily expanded resources and services) and of legal protections -- especially those related to privacy and disability issues --- for test-positive individuals, little benefit results from merely counting individuals through names reporting. We express our strong support

of a national HIV surveillance system that would allow public health officials to rapidly monitor, assess, and respond to present and emerging trends in the epidemic. The Council shares the conviction expressed by many in the field of AIDS that current surveillance systems are inadequate to provide much of the needed data to plan prevention and services activities. However, because states which maintain anonymous testing as an option have higher testing participation, anonymous testing must be preserved to ensure that expanded surveillance is not a disincentive to people to find out their serostatus.

Prisons Subcommittee:

I. The Council recommends that the Director of the Office of National AIDS Policy convene a community and government Summit Meeting on AIDS in Prisons by Fall, 1998. Key constituencies should include, at minimum, participants and presenters from the following constituencies: Community Advocates and Experts, PACHA, Ex-Offenders, Department of Justice, Federal Bureau of Prisons, HRSA, CDC, and international experts, where feasible.

II. The Administration should direct _____ to conduct an HIV surveillance of all prisoners within the federal correction system. Specific funding should be earmarked for this project. The data collected should be used to plan for improving health and psychosocial needs of inmates, to develop appropriate prevention strategies and to make informed decisions with regard to funding allocations.

Background to this resolution: Recent advances in the medical management of HIV disease has resulted in the slowing of the progression of the disease and a decline in the United States of AIDS cases and deaths. The need for an improved HIV surveillance system(s) has become increasingly more critical in order to more accurately monitor the epidemic. While this is true in the general population, it is equally true in the federal correctional system where there is virtually no standardization by which HIV or AIDS is tracked. Note: It is possible that the only data collected by the Federal Government within the correctional setting is AIDS deaths. Should that be the case the last sentence would read, "While this is true in the general population, it is even more true with the federal correctional system where the only AIDS surveillance maintained is on AIDS deaths.

International Subcommittee:

The Presidential Advisory Council on HIV/AIDS recommends that the President support efforts in Congress directed at amending the Embargo

Authority in the Foreign Assistance Act of 1961 so that any such embargo shall not apply with respect to the export of any food, medicines, medical supplies, medical instruments, or medical equipment, or with respect to travel incident to the delivery of food, medicines, medical supplies, medical instruments, or medical equipment. The embargo of such supplies contributes to the suffering of persons with HIV/AIDS and other diseases and is contrary to international humanitarian principles by which the United States should abide.

Research Subcommittee:

Achieving the AIDS Vaccine Goal (full recommendation not attached)

MEMORANDUM FOR DANIEL MONTOYA

From: Todd Summers
Deputy Director
Office of National AIDS Policy
(202) 632-1090

Date: November 16, 1997

Re: PACHA Services Commitee Draft Summary Report

Thanks for passing along a copy of the PACHA Services Committee draft summary report language. I wanted to note two items with which I have a lot of trouble.

First, in the second paragraph of item (1), you state that the Secretary of HHS had taken the idea of expanding Medicaid coverage "off the table." This is not accurate. My understanding is that Secretary Shalala told members of PACHA that she would not support any attempts to alter Medicaid through legislation, believing that the program was still recovering from the last go-around with Congress. Nancy-Ann Minn DeParle has been clear in her meetings with Scott that she is still trying to make an expansion analysis cost neutral, which would allow them to make the change in coverage administratively as opposed to legislatively.

Second, in the first paragraph of item (2) and elsewhere in that same item, I strongly caution against the fundamental questioning of the applicability of Ryan White to meet the needs of people living with HIV/AIDS. I do not believe that Ryan White is any less critical than the day it was passed. To make the argument the way that it is made here could be used to undermine support for the program within Congress, which would be dangerous and irresponsible.

MEMORANDUM FOR DANIEL MONTOYA

From: Todd Summers
Deputy Director
Office of National AIDS Policy
(202) 632-1090

Date: November 16, 1997

Re: PACHA Prevention Commitee Draft Summary Report

Thanks for passing along a copy of the PACHA Prevention Committee draft summary report language. I wanted to note several items which are of concern.

First, the sixth paragraph states, "the administration has maintained outdated and reactionary restrictions" on the content of CDC-funded prevention messages. Is this accurate or are the restrictions at the direct or indirect request of Congress? My guess is that CDC-imposed restrictions relate more to very real political pressures or demands, and not an arbitrary decision to soften materials.

Second, I find this piece lacking in specifics. There are too many vague criticisms, making the summary appear to have been written without a lot of diligent research. It also uses overly-inflammatory terms that do not lend credibility to the message (e.g., "paltry investment," "responded with meekness," "the [CDC] barely monitors," "the administration appears clueless").

Third, the summary fails to address or reconcile the real tension between a full disclosure by CDC of how prevention funds are spent with the likelihood of retribution against prevention efforts that conservatives will find objectionable. Critizing CDC for not adequately monitoring its prevention funding while at the same time attacking them for content restrictions seem to imply a naivete as to the real pressures under which CDC operates. This is not to say that they couldn't do a much better job of articulating the use of and need for prevention funding, but rather that to do so without recognizing the legislative pressure is unfair.

I think this draft needs a lot of work, and would be much more helpful and effective if it offered more specific criticisms and recommendations on addressing complex problems that are not of the Administration's making. For example, has there been any discssion about surrogate markers for assessing prevention program efficacy? How do you support local control over funding while at the same time maintaining adequate federal oversight? Is the PPG system working?

Finally, I question the comments on needle exchange. While I realize that this is a series of comments and recommendations to the Administration, it is unfair to lay all of the blame at its door. The Council knows, or should know, that the Secretary's authority would likely have been removed by Congress within hours of her exercising it. I also think that saying that the President could "lift these funding restrictions with a stroke of the pen" is both unclear and probably unfair. If it is referring, in whole or in part, to needle exchange, than it is technically incorrect since the authority resides with the Secretary. More importantly, this statement expresses a naive perspective that ignores the political reality of a Congress controlled by radical conservatives.

Todd A. Summers
11/19/97 05:44:43 PM

Record Type: Record

To: lsbell @ hugheshubbard.com @ inet, Harndc @ aol.com @ inet

cc: Daniel C. Montoya/OPD/EOP, Scotthitt @ aol.com @ inet
Subject: Prevention committee report

I would like to take a moment to respond to both of your notes in response to my comments on the Prevention Committee Executive Summary.

I am quite surprised at the level of anger and frustration my comments seem to have drawn. First of all, the memos that you received were copies of my comments to Daniel - I wrote them out because we've both been so busy it's hard to meet. I did not take the time to craft the language. Rather, I put them out to Daniel as my impressions of the document from the position of someone who knows perhaps less than PACHA members but more than most intended readers about prevention policy. So I apologize for any perceived insult that may have resulted from my choice of language; none was intended.

Second, I want to make quite clear that I have no interest in asking you or any other group to whitewash legitimate criticisms. My comments were an attempt to convey concern that an overly aggressive tone and missing credit for accomplishments may reduce the effectiveness of the PACHA's report in influencing those that need it.

Daniel C. Montoya
11/19/97 04:46:21 PM

Record Type: Record

To: Todd A. Summers/OPD/EOP

cc:
Subject: Re: Comments from Todd Summers on Services and Prevention

FYI -

dcm
---------- Forwarded by Daniel C. Montoya/OPD/EOP on 11/19/97 04:46 PM ----------

isbell @ HUGHESHUBBARD.COM
11/19/97 02:29:00 PM

Record Type: Record

To: Daniel C. Montoya

cc:
Subject: Re: Comments from Todd Summers on Services and Prevention

Daniel --

Thanks for passing along Todd's comments. I must frankly admit that I find them disturbing. While I fully agree with the need to frame our report in the most productive manner possible, I reject the notion that the Council ought to view the world from the Administration's understandably self-serving perspective. This requires a degree of codependence I don't possess. I also think it would violate Todd's suggestion in our recent process committee conference call that we try to be as productive as possible. It seems evident that the Administration moves on AIDS usually when it's pushed. (By the way, that's not meant as a criticism of the Administration; that's the way politics works, and, besides, I'm a big fan of the President.) Soft-pedaling our message, particularly when all signs seem to indicate a diminution in the priority given to AIDS in Washington, would, in my opinion, be a terrible mistake.

I'm most disturbed, though, by the degree to which Todd's comments stem from ignorance about (a) the Council's prior process and deliberations, and (b) the Administration's own actions (or lack thereof) with respect to the items he addresses. We all ought to be open to criticism, but I generally prefer that such criticism be grounded in an understanding of the issues rather than a knee-jerk defense of the status quo.

I'll largely confine my comments to the Prevention Subcommittee's report (although I would parenthetically question Todd's comments regarding HHS's actions on the proposed Medicaid expansion). To begin with, the subcommittee agreed on its conference call yesterday to make occasional word substitutions. Thus, with respect to the characterization of prevention funding, the word "paltry" has been replaced with "limited." However, the subcommittee unanimously agreed to retain both the existing tone of the executive summary and its substantive criticisms. The subcommittee specifically addressed the concerns which Todd communicated on the process committee conference call and expressly rejected them.

Todd asks whether it is accurate to state that the Administration has maintained "outdated and reactionary restrictions" on federally-funded prevention materials, suggesting that the restrictions respond to Congressional mandates. In 1992, in a lawsuit brought by GMHC, a federal judge invalidated the prior CDC rules that were based on the Helms amendment. Since implementation of the original content restrictions, the CDC, without a specific Congressional mandate, revised the restrictions but maintained essentially the same approach. Apparently, CDC believes it is not currently constrained by Congess in dropping content restrictions altogether, since it proposed exactly the approach we've suggested in the Federal Register in 1993 (dropping the "offensiveness" standard and requiring only that federally-funded materials be scientifically accurate and appropriate for the target audience). The problem, as the Council's own recommendation makes clear, is that the Secretary has inexplicably failed to act on this pending proposed rule change for FOUR YEARS. As for the political pressures on the Administration, AIDS advocates, as well as prior AIDS commissions, lacerated the Reagan and Bush administrations for their elevation of politics over public health. I'm at a loss to explain why we should let the Clinton Administration off the hook for the same sin.

Todd suggests that the Prevention section is "lacking in specifics" and appears to have been written "without a lot of diligent research." When you survey the reality of the situation, it's hard to deal in specifics because few specifics exist. The Administration maintains scientifically untenable restrictions on prevention programs that address sexual transmission, and it withholds funding for the single most effective intervention to address transmission via needle sharing. The Administration's community planning process includes few, if any, checks to ensure that those in greatest need are, in fact, targeted with scarce prevention funding. (In fact, the CDC can't provide a breakdown of how CDC $$ are targeted among the key populations.) Moreover, prevention funding has been going down as a percentage of government AIDS funding. Can you discern a national plan here to make good on the President's promise to halt HIV transmission? I certainly can't. When the administration doesn't have a national prevention plan, particularly after the President has set a lofty national goal of having no new HIV infections, I believe it is incumbent on the Council to say so. This may sound vague or overly simplistic, but it is, unfortunately, the sad truth.

Moreover, this is an executive SUMMARY. It's meant to be general. If one has a need for specifics, we painstakingly document in the text of

our Assessment the administration's response (or, more typically, the lack thereof) to three years of well-researched and thought-through recommendations. The problem here is not lack of specifics, or vagueness, or naivete. The problem is the Administration's failure to act on the vast majority of our recommendations. Had the Administration not ignored the President's own official advisors, we wouldn't be in the position of having to issue such a critical review of our lack of progress.

As for the suggestion that the summary appears to be the product of a lack of diligent research, I can't speak for appearances. All I know is that the Prevention Subcommittee has (a) spent two full days at the CDC, speaking to countless CDC officials regarding the agency's programs, (b) reviewed the available research on needle exchange with a plenary panel and a subcommittee panel of experts, (c) had a joint panel discussion with experts (with the Research Committee) regarding behavioral research, and (d) met with more federal officials on prevention-related topics than I can count. This, of course, doesn't include countless hours of conference calls and meetings, many of them involving federal officials; Terje's upcoming plenary panel presentation on substance abuse; and the special working group on youth that has grown out of the Prevention Subcommittee. Where we've lacked information, we've made specific requests of the appropriate federal agencies (although Daniel can attest to our difficulty in obtaining information through this route). The truth is that the Prevention Subcommittee probably has a greater concentration of expertise on HIV prevention issues than about any other group I can name. Our conclusions are, unfortunately, drawn from experience, not from naivete.

As for Todd's third point, he completely misunderstands what we're saying. We're not asking the CDC to monitor its funding in order to be sure that no controversy arises. We're asking CDC to monitor the public health uses to which state and local health department put these funds. Are these funds appropriately targeted? Are they, in fact, targeted at all? How are individuals and communities being served by federally supported programs? Are programs supported by federal $$ using prevention approaches that have been shown to work? When the answers to the prior questions are unsatisfactory, why doesn't CDC have a mechanism to hold state and local health departments (and their local prevention planning groups) accountable? The statements in the preliminary summary regarding the CDC"s ability to monitor prevention spending certainly won't be the first time CDC has heard these concerns from the Council.

Finally, needle exchange. Can one really assert with a straight face that the predicament the Administration currently faces is not, in large part, of its own making? After all, the Administration sponsored much of the research that has demonstrated the effectiveness of needle exchange, but it has chosen for years to ignore it. Phil Lee spent much of the first term publicly questioning the soundness of the research on needle exchange. After the February report was issued, AIDS advocates, including several members of the Prevention Subcommittee, implored the Administration to develop a political strategy to lift the ban, only to be told there had been no "movement." Yes, there are right-wing nuts in Congress. The Administration, however, has for years made the

calculation that it would rather put off a decision on needle exchange than risk embarrassment on Capitol Hill. Were I working full-time as a White House political operative, I might make the same call. But I'm not holding such a job, and neither are my colleagues on the Council. The Council itself has a job to do, and that's to push the Administration -- hopefully, in the smartest, most effective way possible -- to do the right thing. We've never recommended that the Administration act blindly on needle exchange -- without regard to the political environment -- but it is past the point at which the Administration should have acted on this life-and-death issue. As for why our comments are directed to the Administration and not to the Congress, one need look no further than our name and our mandate. We're the PRESIDENTIAL advisory council. We're here to advise the President, not Congress.

P.S. Daniel, feel free to pass these comments along to Todd and/or Sandy.

From: Daniel_C._Montoya@oa.eop.gov
To: Isbell, Michael; scotthitt@aol.com; nbollman@irvine.org; thenders@glo.state.tx.us; jerryc@wizard.com; harndc@aol.com
Subject: Comments from Todd Summers on Services and Prevention
Date: Wednesday, November 19, 1997 12:06PM

Message Creation Date was at 19-NOV-1997 12:06:00

Todd provided these comments to the Draft Executive Summaries for Prevention
and Services. Though dated November 18th, his comments were made prior to any
refinements made on the Services CC last week and the Prevention CC yesterday.

MEMORANDUM FOR DANIEL MONTOYA

From: Todd Summers
Deputy Director
Office of National AIDS Policy
(202) 632-1090

Date: November 18, 1997

Re: PACHA Services Commitee Draft Summary Report

Thanks for passing along a copy of the PACHA Services Committee draft summary
report language. I wanted to note two items with which I have a lot of trouble.

First, in the second paragraph of item (1), you state that the Secretary of HHS
had taken the idea of expanding Medicaid coverage &off the table. 8

Presidential Advisory Council on HIV/AIDS
Executive Summaries

Prevention Subcommittee

More than 16 years after the epidemic was first recognized and five years into an administration that promised leadership in the effort to "reduce the number of new infections until there are none," the United States still lacks a coherent, effective national strategy to prevent HIV transmission. The results are appallingly predictable. More than 40,000 Americans become infected with HIV each year. 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.

During the early years of the epidemic, former Surgeon General C. Everett Koop and eminent organizations, such as the Institutes of Medicine and the Presidential Commission on AIDS, 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.

Subsequent research has confirmed the validity of these recommended strategies. 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 to address sexual behavior are most effective when they provide explicit information, 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. One widely-cited study by leading researchers, for example, determined that needle exchange reduced HIV infection rates by 50 percent or more.

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. While the societal costs of AIDS have grown exponentially, HIV prevention has declined as a percentage of government AIDS-related spending.

Worse still, the Administration makes exceedingly poor use of its paltry investment in HIV prevention. The Administration has maintained outdated and reactionary restrictions on the ability of federally-funded HIV prevention programs to provide explicit information to those at greatest risk, encouraging HIV prevention educators to censor themselves in order to retain their federal funding. Moreover, rather than ensure that scarce prevention funds actually go to those in greatest need, the Centers for Disease Control and Prevention barely monitors the uses to which federal HIV prevention funds are put by state and local health departments.

The Administration's timidity in the face of this frightening health emergency is most powerfully exemplified by the continued prohibition on federal funding for needle exchange programs. The President could lift these funding restrictions with a stroke of the pen, yet he has failed to do so. Even though 50 percent or more of new HIV infections are traceable to substance use, the Administration appears inexcusably and inexplicably unwilling to respond to this worsening crisis.

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 half-hearted, 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, the Administration has no plan for achieving this lofty 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.

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Research Subcommittee

The President's leadership is to be highly commended for his efforts to begin the work of developing an AIDS vaccine. The President's announcement of the goal of an AIDS vaccine within the decade in May, 1997, and the focus on an AIDS vaccine during the G-7 meeting is unsurpassed and 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 while not completely accomplished are being reviewed and addressed. The Council is committed to continuing the work that has begun and will be submitting additional recommendations during our December, 1997, meeting in order to reach the goal of an AIDS vaccine.

The Food and Drug Administration (FDA) is to be commended for their efforts to address some of the gender issues 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 drugs on children. Again the FDA has acted on this issue and is to be commended for it's efforts to see that labeling of marketed prescription drugs includes pediatric data. However, another recommendation calling for an on-going review of the numbers of children actually enrolled in NIH sponsored clinical trials has not been addressed or implemented. ? what do they mean?

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 yet to be achieved. OK

While some work on microbicides has been accomplished, the three recommendations on microbicide research, approved by the Council in December, 1995, have not been fully addressed. No new funds have been allocated for microbicide research, no new full-time equivalents (FTEs) have been designated to the effort, no new Requests for Applications (RFAs) have been issued which might interest new investigators in the field, and a public health consensus panel to assess the efficacy of available spermicides and other licensed products has not been convened. ?

(100 x 10^6 was promised by Sec, over a 4 year period @ Vancouver

The recommendation for ongoing mechanisms to ensure the rapid translation of breakthrough research findings into clinical practice has been addressed by NIH in the areas of the biomedical research findings. NIH has several mechanisms in place that provide rapid dissemination of these findings. In the area of behavioral and social science, mechanisms need to be developed that also provide rapid translation/dissemination of research findings. It is the Council's intent to address this issue in future recommendations.

Since the work of the Council began in July, 1995, the Research Committee has made 17 recommendations, approved by the full Council, addressing some of the issues on the above topics. Several of these recommendations have been acted upon with vigor, with resultant resolution of the problem being addressed. Other recommendations are currently being reviewed or addressed, while others have been largely ignored.

~5 Centers Nationally

Centers for AIDS Prevention Studies (CAPS)

~~Proposed~~ goal is to disseminate behavioral & social science research that has proven efficacy.

In addition to multiple meetings they have a web site & an ongoing mailing of Newsletters that reviews the recently published literature by high risk group.

Eg: Prison ca
- Adolescents
- Adolescent Gay ♂
- ♀
- Gay ♂ men of color
- Heterosexual Black, Hisp, Asian, NA, Pacific Islander

Services Subcommittee

The following issues constitute major current priorities for the Services Committee:

1) Access to the new therapies.

A year ago, and following promising trials with the new combinations therapies, HHS undertook to develop new HIV treatment guidelines. Because early intervention appeared at the time to be a likely recommendation, the committee and the full Council urged that the Administration announce simultaneously with the new guidelines a strategy for providing insurance coverage (or other means) to ensure that all those who could benefit medically from the new therapies would have financial access to them. We saw this primarily as a humane approach, but because of avoided costs associated with disease progression, and even a return to work and taxpayer status for many, we saw it as a potential cost-benefit as well. A new strategy for access is especially important for Medicaid, the largest payor for HIV/AIDS medical services, because people with HIV are precluded from Medicaid coverage for early intervention because only disease progression triggers the disability determination which in turn triggers Medicaid coverage. What was previously seen as a benign policy becomes, in light of the new treatments, perverse. ← why? - however any other disease for which we develop guidelines but do not necessarily pay RX at

We were heartened by the Vice President's call for an exploration of the feasibility of expanding Medicaid coverage to provide access to the new therapies, but stunned to hear from the Secretary of HHS in a recent meeting that she had taken this idea "off the table." Moreover, she has offered only a vague assurance that the same end could be assured through an increased appropriation in the AIDS Drug Assistance Program (ADAP). We do not have at this time from HHS a reliable cost estimate for such expansion of ADAP, nor a political strategy. If we are intensely interested in this turn of events, perhaps it is related to the fact that it was the Congress, not the Administration, that proposed increased ADAP funding in the 1997-98 federal budget.

- ADAP
- HTN
- CAD
- CANCER all typ
- CVA's

Come on too hour

The process and focus must maximize input

This flailing about, without apparent commitment, and certainly without a plan for access, is causing unnecessary human suffering, and hastening death, for many people with HIV/AIDS, and must be addressed at once.

2) National policy dialogue.

Nearly a year ago, again in light of the new therapies, the Committee and the council called for a national dialogue on how the federal government structures and pays for medical and support services for people with HIV/AIDS. The Ryan White CARE Act has been a major vehicle for this purpose, but it has been structured to address a disease that proceeds to death at a relatively rapid rate. With the new therapies, and the possibility of deferring symptomatic episodes, and perhaps for

In actual fact our entire effort has been focused for 3-4 years on T'ing the # of individuals entered IN Care SERVICES. Indeed, this is the predominate reason we have seen drops IN AIDS case rates

HHS to have focused meeting on this specific issue in Feb - March.

many, turning HIV/AIDS into a chronic disease, the fundamental assumptions of Ryan White and other federal policies bear re-examination. Each Agency is dealing with this now

With support from the Vice President's office and the Office of National AIDS Policy, a national policy dialogue process was developed by the prestigious Keystone Center. This process has now been blocked by HHS, with no alternative process proposed. In the absence of such a process and as the epidemic and new therapies evolve, Ryan White and other federal programs may be increasingly ill-suited to meeting the critical medical and social service needs of people with HIV/AIDS. This will unnecessarily invite criticism from AIDS advocates, and even the Congress, of programs that have been generally effective, but that need to be restructured to continue their effectiveness.

Since JAN 1995

~~Effort~~ white, rich-male perspective

HHS Intensed Dialogue Efficacy of Fed Programs
- CDC/NIH/HRSA/SAMHSA/AHCPR/FDA
- Convened by OHAP
- Culminates in meeting Feb - March.

Once completed → expanded dialogue with community input grps

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.

Not true

Additionally, the Center for Disease Control 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.

3

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.

CDC/OTMR

Scheduled to occur. Early '98

Prisons Subcommittee

The Committee on Prison Issues has examined a number of issues. Among these are compassionate release programs, educational programs, protective barriers and harm reduction, standards of care and implementation of the recommendations of the National Commission on AIDS (which the Department of Justice states it has not had the opportunity to review - memo, 5/9/97). In general, the responses we have received from representatives of the Federal Bureau of Prisons have been neither prompt nor direct generating great concern over a number of issues involving HIV/AIDS in Correctional settings. Among the more noteworthy are the following:

1. Compassionate Release.

Compassionate release for severely infected individuals is reasonable and humane, yet this option is rarely considered in federal prisons. (DoJ states that revisions are not necessary - memos, 7/8/97 & 10/15/97). The appropriate codes must be reviewed and revised in order to make this option more available to terminally ill inmates who do not pose a threat to society.

2. Protective Barriers.

Federal officials are simply unwilling to discuss the use of protective barriers for prisoners (stating this is inappropriate for inmates; "condoms and/or dental dams are not medically necessary..." - memo, 7/8/97 & 10/15/97). Another argument against protective barriers is that such devised would create an "environment in which control would be difficult." What we do know from the most recent reported data of the CDC & DoJ is that in many Correctional settings the incidence of STD's is high. Prisoners are having sex. We feel it is imperative that we address the reality and attempt to curb not only the spread of HIV but also Hepatitis and other STD's. Successful models for condom distribution are in place in several facilities are worth examining/piloting in federal facilities.

3. Substance Use.

In the context of more comprehensive Harm Reduction approach to HIV management, resources for substance use treatment are essential yet not easily accessible in federal prisons ("inmates who volunteer for treatment "are admitted into residential substance abuse programs in sequential order based upon release date - memo, 10/15/97). Review of waiting periods and program content should be conducted and necessary program expansion planned in order to accommodate inmates within a reasonable time period.

HIV Disease has demanded a reevaluation of the ways in which we have traditionally approached prevention, education, psychosocial/medical intervention, and treatment. While the Federal Bureau of Prisons has developed policies and procedures for dealing with many HIV issues, testimony from those who are or who

have been incarcerated reveal an intransigence at the level at which these policies are carried out. Access and treatment for chemical dependency, varies widely. Case management with appropriate referral and follow-up upon release is inconsistent. Model programs have been funded in select sites and are worthy of examination and expansion into other facilities. The Subcommittee on Prison Issues expresses concern that HIV in Correctional settings may not be being addressed from a public health perspective. The lack of investment in HIV prevention and care while individuals are incarcerated is a significant barrier against reducing the spread of HIV within Correctional settings and into the general population.

Agree this needs to be better coordinated with HHS related programs at the State & Local levels.

Other issue: crack House legislation & dialogue w/ DOJ resulting in

A. Review of medical standard of care (HIV STD TB) recently released by DOJ/Fed Prisons medical director (Ken Montoya)

~~B. [redacted]~~

B. DOJ will refer HHS for assistance Sec → Att General → Montoya

International Subcommittee

The Presidential Advisory Council is quite 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. Thus, it should have been thoroughly assessed, and a current international strategy should have been promptly developed.

Given the ever-growing and ever-worsening global pandemic, the failure of the Department of State to assume a leadership role within the U.S. government and the global community is inexcusable and unconscionable.

Additionally, insofar as the United States Agency for International Development constitutes the primary U.S. effort to respond to the international AIDS' crisis, the failure of the President to seek increased appropriations for USAID from Congress does not make any sense to the Council. true? y

We emphatically urge 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. We request that the State Department report on its assessment of its 1995 International Strategy on HIV/AIDS and the status of the development of a current strategy.

The Advisory Council considers the depth and breadth of the global AIDS crisis to constitute a direct threat to the economic and strategic interests of the United States, and thus requires a commensurate level of action by the United States government.

Sandy has begun a dialogue w/ all principals at USAID; WHO; HHS; and multiple NGO's. If this is a high priority of the WH it is in direct conflict w/ domestic allocation decisions and a prioritization needs to be forthcoming.

NO mention of Sandy's efforts

Presidential Advisory Council on HIV/AIDS

Proposed Recommendations
for Adoption at the December 1997 Meeting

Discrimination Subcommittee:

The Administration should work with Congress to create stronger protections for medical privacy, and should revise its legislative proposals on the subject to permit law enforcement authorities access to patient records only after they have obtained a warrant or meaningful and informed patient consent.

Prevention Subcommittee:

I. The President shall instruct the Secretary to develop oversight guidelines within 60 days of the re-evaluation of Model Paraphanalia and Prescription code directed towards the lifting of the federal ban on Needle Exchange in 120 days.

II. In recognition of the inadequacy of the current HIV surveillance system and the need to have better information about current HIV infections a quickly as possible, the Council urges the President to initiate a study through the CDC of the methodologies and efficacy of various HIV reporting mechanisms, including, but not limited to, random sampling and unique identifier systems. We also urge the President to convene a National Surveillance Meeting including, at a minimum, the CDC, HRSA, HCFA, the Department of Justice, and state representatives where non-named reporting occurs to address in a holistic way the implications of moving to nationwide HIV reporting and to oppose the apparent federal trend towards quick implementation of name-based HIV reporting. The meeting agenda should include review of the full range of reporting mechanisms, incentives and disincentives to HIV testing in each system, identification and assessment of built-in gaps and biases, liabilities and benefits to individuals and to public health, goals and objectives of HIV reporting, and links to preserving concurrent anonymous testing programs.

Background to this resolution: HIV reporting, in and of itself, does not fill the significant gaps that exist in understanding the spread of HIV. In the absence of federally assured medical services whose goal is getting people into early, aggressive treatment (inclusive of necessarily expanded resources and services) and of legal protections — especially those related to privacy and disability issues — for test-positive individuals, little benefit results from merely counting individuals through names reporting. We express our strong support

of a national HIV surveillance system that would allow public health officials to rapidly monitor, assess, and respond to present and emerging trends in the epidemic. The Council shares the conviction expressed by many in the field of AIDS that current surveillance systems are inadequate to provide much of the needed data to plan prevention and services activities. However, because states which maintain anonymous testing as an option have higher testing participation, anonymous testing must be preserved to ensure that expanded surveillance is not a disincentive to people to find out their serostatus.

Prisons Subcommittee:

I. The Council recommends that the Director of the Office of National AIDS Policy convene a community and government Summit Meeting on AIDS in Prisons by Fall, 1998. Key constituencies should include, at minimum, participants and presenters from the following constituencies: Community Advocates and Experts, PACHA, Ex-Offenders, Department of Justice, Federal Bureau of Prisons, HRSA, CDC, and international experts, where feasible.

II. The Administration should direct _____ to conduct an HIV surveillance of all prisoners within the federal correction system. Specific funding should be earmarked for this project. The data collected should be used to plan for improving health and psychosocial needs of inmates, to develop appropriate prevention strategies and to make informed decisions with regard to funding allocations.

Background to this resolution: Recent advances in the medical management of HIV disease has resulted in the slowing of the progression of the disease and a decline in the United States of AIDS cases and deaths. The need for an improved HIV surveillance system(s) has become increasingly more critical in order to more accurately monitor the epidemic. While this is true in the general population, it is equally true in the federal correctional system where there is virtually no standardization by which HIV or AIDS is tracked. Note: It is possible that the only data collected by the Federal Government within the correctional setting is AIDS deaths. Should that be the case the last sentence would read, "While this is true in the general population, it is even more true with the federal correctional system where the only AIDS surveillance maintained is on AIDS deaths.

International Subcommittee:

The Presidential Advisory Council on HIV/AIDS recommends that the President support efforts in Congress directed at amending the Embargo

Authority in the Foreign Assistance Act of 1961 so that any such embargo shall not apply with respect to the export of any food, medicines, medical supplies, medical instruments, or medical equipment, or with respect to travel incident to the delivery of food, medicines, medical supplies, medical instruments, or medical equipment. The embargo of such supplies contributes to the suffering of persons with HIV/AIDS and other diseases and is contrary to international humanitarian principles by which the United States should abide.

Research Subcommittee:

Achieving the AIDS Vaccine Goal (full recommendation not attached)

TAS-

FYI

Dan

Circle page 3
1st paragraph

S/S 9714151

United States Department of State

Washington, D.C. 20520

November 5, 1997

UNCLASSIFIED

MEMORANDUM FOR DANIEL C. MONTOYA
EXECUTIVE DIRECTOR
PRESIDENTIAL ADVISORY COUNCIL ON HIV/AIDS

Subject: Status of Department of State Policies on HIV/AIDS Testing for Foreign Service Personnel

In response to the inquiry from the Presidential Advisory Council of July 22 on HIV/AIDS, I have consulted with our Office of Medical Services in regard to mandatory HIV testing and am happy to provide you with the following information.

The Foreign Service Act of 1980 directed the Secretary to establish a health care program to promote and maintain the physical and mental health of members of the Service and their families. Section 101(4) of the Act specifies that "the members of the Foreign Service should be available to serve in assignments throughout the world." Based on the Act, worldwide availability is a criterion for entrance into the Foreign Service. To ascertain whether recipients of conditional offers of employment in the Foreign Service can meet the criterion of worldwide availability, they must undergo a medical examination prior to appointment. This examination is intended to identify whether an individual has any of a variety of diseases and/or medical conditions that would preclude that individual from being able to serve anywhere in the world. Individuals who are determined to have such diseases or conditions are given limited medical clearances and thus disqualified from entrance into the Foreign Service, subject to the waiver process mentioned below. One part of the medical examination consists of laboratory studies that include both HIV and ELISA tests. An applicant who is determined by these tests to be HIV-positive is considered not to be available for assignment worldwide. HIV is only one of many medical problems or conditions that would disqualify an applicant from the Service because of the resulting limitations on worldwide availability.

In the Foreign Service context, there are three reasons why HIV positive individuals are not worldwide available medically, and thus must be identified in advance through mandatory testing:

1. ACCESS TO ADEQUATE MEDICAL FACILITIES: It is essential for a person infected with HIV to have quick access to high quality medical resources. Most overseas posts do not have access to the medical resources necessary to maintain the health of individuals infected with HIV. This is particularly important in today's medical environment where new HIV therapies can prolong life and improve the quality of life of HIV infected patients. Quality medical care has a positive impact on the evolution of the HIV infection in many individuals, especially those who are newly infected. Early diagnosis and prophylactic treatment of HIV related opportunistic infections is also paramount.

2. ACTIVATION OF A LATENT HIV INFECTION: There is a strong suspicion among experts that exposure to other infectious diseases can activate latent HIV and cause progression to AIDS. The Office of Medical Services (M/DGP/MED) will therefore not support the assignment of a person infected with HIV to a post where there is a high incidence of infectious disease such as tuberculosis and infectious diarrhea.

3. LIVE VACCINE: For many posts where the incidence of contagious diseases is high, vaccination with live vaccines is required. Live vaccines, however, are contraindicated in patients infected with HIV especially those whose immune systems have been weakened. Therefore, M/DGP/MED, in accordance with accepted sound medical practice, will not risk administering live virus vaccines to a person who is infected with HIV.

The Department's policy of mandatory HIV testing was supported by the U.S. District Court for the District of Columbia in 1987. The district court was satisfied that the Department had serious grounds for concern about additional risks that persons with HIV encountered in many foreign posts due to inadequate diagnostic and treatment centers. The court stated: "The Rehabilitation Act does not require the Department of State to ignore the obvious relevance of HIV infection to its qualification of Foreign Service employees for long terms of worldwide duty abroad."

Foreign Service employees who become HIV positive subsequent to their entrance into the Foreign Service are issued limited medical clearances. In-service limited clearances are issued to individuals who have one or more medical conditions that require periodic and specialized medical evaluation and/or treatment, or whose medical condition would be aggravated by certain environmental conditions. Many conditions can result in a limited clearance, such as asthma, insulin dependent diabetes, coronary artery disease, chronic active hepatitis, and HIV, among many others. When an employee holds a limited clearance, potential assignments are considered on the basis of the capability of local resources for monitoring and care of the medical condition or diseases and on whether or not service in that environment would place the person at increased risk. Every effort is made to find posts to which HIV-positive employees can be safely assigned, as is the case for employees with other medical conditions or diseases that result in limited clearances. HIV-positive employees may serve, and in fact are currently serving, overseas in countries where local health providers and medical facilities can follow their conditions.

Family members of applicants and family members of Foreign Service members who are found to be HIV positive are also issued limited medical clearances. The clearance status of an applicant's family members does not have any effect on whether the applicant is accepted into the Foreign Service, but a family member with a limited medical clearance may not be able to go to a particular post to which the Foreign Service member with an unlimited clearance is assigned.

In the event an employee or family member with HIV develops AIDS, the medical clearance may be changed to the category of Class 5, "Not Cleared for any Overseas Assignment", for individuals found to have medical conditions which require specialized medical care best obtained in the United States. The final clearance decision is based on multiple factors specific to the individual. Among those factors considered for a person with AIDS are the CD 4 lymphocyte count, the patient's history of previous opportunistic infections, the prevalence of infectious diseases at the proposed post, the ability of local providers to treat AIDS and AIDS related conditions, local support available to the individual at an overseas post, and whether the individual prefers to stay in the United States rather than be assigned to one of the few posts where

adequate treatment is available. A Class 5 clearance, which prohibits service overseas, is issued only after extensive consultation with the individual and his or her physician, and careful evaluation of post capabilities.

Applicants who receive a limited and thus disqualifying medical clearance may request a waiver of the preemployment medical standards. In such cases, the applicant authorizes disclosure of information about his or her medical condition to an Employment Review Committee, which reviews the reasons for the limited clearance and the extent to which the underlying medical condition would limit the applicant's worldwide availability. In the case of in-service limited or Class 5 medical clearances issued to employees or family members, employees may also request that a three-physician panel convened by the Medical Director review the clearance decision. The standard for review is whether there would be undue risk to the employee or family member at the proposed post. An employee may also seek an administrative waiver for a proposed post assignment through the employee's bureau, employing agency, or the Director General of the Foreign Service. It should be noted that the medical information on which clearance decisions are made is not disclosed to Personnel or other parts of the Foreign Service without the individual's consent, thus protecting medical confidentiality.

Please feel free to contact me if you should have further questions.

William J. Burns
Executive Secretary

HUMANITAS, INC.

November 4, 1997

Daniel C. Montoya, Executive Director
Presidential Advisory Council on HIV/AIDS
Office of National AIDS Policy
818 17th Street, NW, Suite 820
Washington, DC 20006

Dear Mr. Montoya:

At Dr. Hayman's request, I am enclosing the Executive Summary for the evaluation study conducted to assess risk behaviors and outcomes among HIV positive youth in Job Corps. Should you have any questions or require additional information, please give me a call.

Sincerely,

Lura Myers
Vice President

cc: Charles R. Hayman, MD
National Medical Director, Job Corps

Job Corps Health Support Project ■ 8630 Fenton Street, Suite 910 ■ Silver Spring, MD 20910
301-608-3290 (Phone) ■ 301-608-3296 (Fax)

Evaluation Of HIV Policy In The Job Corps: A Four-Year Study to Assess Risk Behaviors and Program Outcomes in HIV-Positive and HIV-Negative Participants

FINAL REPORT

Prepared by:

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As part of subcontract to
Johnson Bassin & Shaw, Inc.
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Submitted to:

National Medical Director
Office of Job Corps
U.S. Department of Labor
Employment & Training Administration
Washington, DC

August 1, 1996

EXECUTIVE SUMMARY

I. Background

1. Research Questions

QUESTION A. Are HIV-positive participants in Job Corps at high risk of infecting others and engaging in other problem behaviors? How do they compare to the drug-positive HIV-negative controls?

QUESTION B. What is the impact of Health Services assessment and case management processes on the risk behaviors and program performance of high-risk participants in Job Corps, particularly the HIV-positive students?

QUESTION C. Can we successfully identify, at intake, students who are likely to pose problems in Job Corps and who will continue to show high risk health behaviors when they leave the program?

2. Methods

One-on-one interviews with students at three time periods: 1) entry into Job Corps (the "intake" period), 2) termination from the program (the "exit" period), and 3) six months after leaving Job Corps (the "follow-up" period). Average length of stay in Job Corps was 5.8 months. The follow-up interviews took place, on average, approximately one year after participants entered the program.

To measure participants' health risk behaviors, a relatively new instrument was tested; the 163-item Problem Oriented Screening Instrument for Teenagers (POSIT). The POSIT can be administered by center staff with relatively little training and does not require a high degree of literacy for participants to complete, since it focuses on behavior and uses a Yes/No response set. The questions cover such areas as alcohol and substance abuse, drinking and driving, health, accidental injuries, sexual behavior, violent or aggressive behavior, suicidal ideation or attempts, family or parental supervision, impulse control, mood such as depression or anxiety, stressful life events, and school or academic performance. For the exit and follow-up interviews, the POSIT was administered by research staff.

3. Sample

One hundred eighty-five newly entered students comprised of 61 HIV-positive students, 62 HIV-negative/drug-positive and 62 HIV-negative/drug-negative students selected from 12 participating Job Corps centers between June 15, 1993 and June 30, 1994. One hundred percent of the sample were successfully traced for both exit and follow-up interviews.

II. Summary of Results

QUESTION A. **Are HIV-positive participants in Job Corps at high risk of infecting others and engaging in other problem behaviors? How do they compare to the drug-positive HIV-negative controls?**

FINDING A1. Students in all three study groups have problems that can lead to risky behavior and HIV transmission. However, the HIV-positive group as a whole is not a high risk group simply by virtue of HIV status. This group is extremely heterogeneous in behavior and differences in risk must take into account other factors, particularly drug use.

FINDING A2. There are distinct and different profiles of risk factors between the three study groups at intake: The HIV-positive group report more behaviors associated with sexual risk while the drug-positive controls report more violence, delinquency, and drug use risks, and the drug-negative controls report affective (mood, anxiety, depression, suicidal ideation) risk factors.

FINDING A3. Among the HIV-Positive students, those who are drug-negative do not appear to present a high degree of health risk for either themselves or others in Job Corps.

FINDING A4. On the other hand, those HIV-positives who are also drug-positive (the "double-positives") are at highest risk for a host of health risks, including transmission of HIV to others, continued substance abuse, and violence. They likely contracted HIV through drug-use, either directly by IV drug use or by drug use that was secondary to heterosexual contact. The double-positive group is in many ways the most at risk for untoward health consequences.

FINDING A5. HIV-Negative students who test positive for drugs at intake are not already infected with HIV but they are at highest risk of becoming infected due to their reported risky behaviors, including drug use, sexual activity and violence while attending the program. They are also least likely to utilize Job Corps Family Planning programs, which suggests that these drug-positive students may not be getting sufficient screening for health problems or programs aimed at preventing pregnancy and sexually transmitted diseases. Given their high risk status, there appears to be a gap between their behavior and their utilization of the necessary services that may prevent infection.

FINDING A6. Drug use rather than HIV status appears most influential in identifying differences between students along the continuum of health risk. The drug-positive control group report the

most risk behaviors, in the areas of drug use and violent behavior, at both exit and follow-up periods.

CONCLUSION: **There are more differences along drug use status than there are among HIV status, suggesting that drug test status is a more important predictor of risk behaviors at intake compared with HIV status. Seropositive students entering Job Corps are not necessarily at greater risk than the general population of non-HIV entrants. However, those who test positive for both HIV and drug use represent a subgroup of the highest risk participants.**

QUESTION B. **What is the impact of Health Services assessment and case management processes on the risk behaviors and program performance of high-risk participants in Job Corps, particularly the HIV-positive students?**

FINDING B1. Satisfaction with the program is highest among youth who stay longer in the program and who have high utilization of the services during their stay.

FINDING B2. The overall POSIT (Problem-Oriented Screening Instrument for Teenagers) risk score and each subscale score (except mood) decreased from the intake to the exit interview. The decrease in risk behavior during their stay in the program is significantly related to length of stay so that the longer students remain in the Job Corps program, the more their risk scores decreased when they left the program. This provides some evidence for the short-term gains in positive behavior that appear due to the students' exposure to Job Corps programs.

FINDING B3. Six months after leaving Job Corps, participants still show a significant reduction in risk behavior compared to their intake levels and they made some positive life changes, including higher levels of employment and continuing education, lower crime, and safer sexual behavior. However, the results do not provide strong evidence that the program itself was responsible for these changes at this later time, as length of stay does not appear to influence the rate or the degree of change over time in participants' risk behaviors.

FINDING B4. The findings support a key objective of the HIV Policy; that is, to provide HIV-positive students with extensive case management, monitoring and involvement in Health Services throughout their stay in Job Corps. Further, HIV-positive students use more on- and off-center health services than the drug-positive controls. HIV-positives receive more medical case

management and more mental health counseling, and they are more likely to go to Health Services just to talk.

FINDING B5. The results indicate a consistent pattern of change in risk behavior over the three time periods. Risk scores for the POSIT as well as other problem indicators are the highest at intake and they become the lowest during participants' stay in the program. Six months later, participants' scores for health risk rise, but never attain the high level they were at program intake, which suggests that participants show a long-term reduction in behaviors that places them at risk for HIV and other health and social problems.

CAVEAT Evidence indicating that the impact of the program does not appear to be sustained in the longer-term is limited by the study design that relied primarily on levels of exposure to the program via length of stay to determine program impact. Since no control or comparison group was employed to hold program participation constant, it is difficult to conclude that the program was responsible for the changes. The results show that participants made changes in their lives and that these changes were sustained six months after they left the program, but there is weaker evidence that the program *caused* these changes, due to the lack of a true comparison or control group. An alternative hypothesis, not tested in this study, is that participants made the changes by virtue of their becoming older and hence were not engaging in the same level of risk behaviors that they did when they were younger (at the beginning of the study).

CONCLUSION: **Participants made positive changes in their lives and reduced their risk behavior from intake to program exit and these changes were sustained six months after they left the program. There is modest evidence suggesting that participation in the program was responsible for these changes in the short-term (immediately upon leaving the program) but there is no support that the program was responsible for these changes in the longer-term (six months later). The research design limits the study's ability to make a causal link between the program and the changes in behavior.**

QUESTION C. **Can we successfully identify, at intake, students who are likely to pose problems in Job Corps and who will continue to show high risk health behaviors when they leave the program?**

FINDING C1. Youth who are at high risk at intake, according to the POSIT, are more likely to be a danger to themselves and others during their stay in the program and six months later they are most likely to continue engaging in high risk behavior. At the exit and follow-up interviews, participants who are high risk at intake report greater risk for suicide, HIV transmission and violent behavior. The intake POSIT is also a strong predictor of follow-up scores for impulse control and social and for lesser amounts for some of the other subscales. These relationships hold even after controlling for age, gender, study group and length of stay.

FINDING C2. The POSIT given at intake to Job Corps is not only a good predictor of later scores on the POSIT, but it is also a good predictor of other, real-world indicators of Job Corps participants' risk behavior and outcomes, as measured by other self-reported items. Participants identified as being at high risk at intake are less likely to report always using a condom, they are more likely to report alcohol use within the most recent thirty-day period, and they are more likely to be charged with a crime.

FINDING C3. Scores on the POSIT for depression and suicide risk are highly related to scores on the Beck Depression Inventory. This suggests the POSIT has good validity in identifying depressed, anxious and suicidal students. Further, compared with the POSIT, the Beck Depression Inventory is relatively restricted in its predictive utility to those variables expected to be related to depression, such as mood, anxiety, suicide risk.

CONCLUSION: **These results suggest that the POSIT is a useful instrument for identifying high risk in adolescents entering Job Corps and appears to be a good predictor across a relatively "broad-band" of risk factors (depression, violence, drug use, sexual behavior, social competence). It is relatively simple to administer by center staff and generally can be completed in 20 minutes. It also does not require a high level of literacy since the items are behaviorally-based and rely on a Yes/No response set.**

III. Recommendations

I. Policies should be directed at either providing these students with more support and monitoring while they attend the program or there should be some consideration towards limiting their participation in Job Corps.

II. The POSIT should be considered for general-use screening in Job Corps centers. However, it should undergo additional psychometric testing so that cut-off scores based on a standard, probability sample are obtained. Finally, the length of the instrument could be shortened by approximately 25% without loss of reliability.

Prevention Committee:
Mike Isbell
Alexander Robinson

Research Committee:
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Helen Miramontes

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Discrmination Committee:
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DEPARTMENT OF HEALTH & HUMAN SERVICES

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NOV - 4 1997

Daniel Montoya, Executive Director
Presidential Advisory Council on HIV/AIDS
808 17th Street, N.W.
Washington, D.C. 20006

Dear Mr. Montoya:

Thank you for allowing the Agency for Health Care Policy and Research (AHCPR) the opportunity to provide feedback regarding, the Presidential Advisory Council on HIV/AIDS Prevention Subcommittee's assessment, of the Administration's response to its most recent recommendations.

As you may be aware, AHCPR's mission is to generate and disseminate information to improve our health care system. AHCPR accomplishes this mission via a number of complementary goals, which include:

- Helping consumers make informed choices;
- Determining what works best in clinical practice;
- Measuring and evaluating quality of care;
- Improving the cost-effective use of health care resources;
- Assisting health care policymakers; and
- Building and sustaining the nation's health services research infrastructure

Keeping these goals in mind, we are providing feedback regarding the Prevention Subcommittee's recommendation III.C.1. While cognizant that you have asked us to comment on the Subcommittee's *assessments* of its recommendations, because of the absence of any assessment under item III.C.1, we are responding directly to the recommendation itself.

Recommendation III.C.1 calls on the President to direct the Secretary of Health and Human Services, with the National Institutes of Health, the Office of AIDS Research, and the Centers for Disease Control and Prevention to develop a coordinated and comprehensive prevention science agenda that includes biomedical, behavioral and social science interventions. We believe this recommendation is on the right track. To enable a fully coordinated prevention science agenda, however, this recommendation should also encompass the relevant activities of the AHCPR and the scientific contributions of health services research.

In the recent past, for example, AHCPR-sponsored research has demonstrated that:

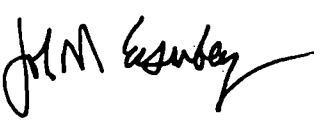
- Preventive therapy for *Pneumocystis Carinii* pneumonia reduces hospitalization and improves outcomes in persons with HIV;
- Primary care physicians often fail to recognize important clinical signs of HIV infection, such as Kaposi sarcoma;
- Disadvantaged groups lag behind other patients in receipt of new HIV treatments; and that
- Rural AIDS cases have risen dramatically among some groups, especially among women, blacks, and adolescents.

The AHCPR also sponsors two other long-term efforts intended to foster greater understanding of, and lead to more effective prevention of, HIV and associated secondary infections. These include:

- The HIV Cost and Services Utilization Survey (HCSUS), a multimillion dollar longitudinal study gathered from a national sample of 3,000 HIV infected individuals from both urban and rural environs that examines the organization, delivery, costs, and outcomes of health services for people infected with HIV.
- The AHCPR also houses the operations of the U.S. Preventive Services Task Force, an independent advisory panel that produces the *Guide to Clinical Preventive Services*, an important mechanism to reach community clinicians with HIV/AIDS prevention strategies.

Details of these and other relevant AHCPR-funded research on HIV/AIDS are enclosed for your information. Should you have any questions or comments relating to either this response or to AHCPR's HIV/AIDS research portfolio, do not hesitate to contact me at (301) 594-6662, or AHCPR's HIV/AIDS Coordinator, Phyllis Zucker at (301) 594-2453.

Sincerely,



John M. Eisenberg, M.D.
Administrator

Enclosures

AHCPR-Funded Study Finds Progression of HIV Disease Not Related to Race, Sex, or Drug Use

Press Release Date: September 20, 1995

A new study being published in the September 21, 1995, issue of *The New England Journal of Medicine* examines the relationships of race, sex, and drug use to progression of HIV disease. The rates of progression of HIV infection and survival have been reported in a number of earlier studies to differ between sociodemographic groups, though it has remained unclear whether these differences reflected biologic differences or differences in access to medical care.

The researchers concluded that among patients with HIV infection who received medical care from a single urban center, there were no differences in disease progression or survival associated with sex, race, injection-drug use, or socioeconomic status. Differences found in other studies may reflect differences in the use of medical care.

Researchers at The Johns Hopkins University School of Medicine in Baltimore, supported by an AHCPR research grant, measured disease progression and survival in a cohort of 1,372 patients who were seropositive for HIV, and who were treated at a single urban center. Median follow-up was 1.6 years. They calculated the rates of survival for the entire cohort and the rates of progression to the acquired immunodeficiency syndrome (AIDS) or death in 740 patients who presented without AIDS.

In the entire cohort, a lower CD4 cell count, a diagnosis of AIDS, older age, and the receipt of antiretroviral therapy before enrollment were associated with an increased risk of death. The use of prophylaxis against pneumocystis pneumonia, zidovudine use after enrollment, and having a job at base line were associated with lower risks of death. The researchers found no significant difference in survival between men and women, blacks and whites, injection-drug users and those who did not use drugs, or patients whose median annual incomes were $5,000 or less and those whose incomes were more than $5,000. They found no relation between disease progression and sex, race, injection-drug use, income, level of education, or insurance status.

Note: The article in the September 21, 1995 issue of *The New England Journal of Medicine* is entitled "Race, Sex, Drug Use, and Progression of Human Immunodeficiency Virus Disease," by Richard E. Chaisson, MD, Jeanne C. Keruly, BSN, and Richard D. Moore, MD, MHSc.

For assistance in arranging interviews, or for information on other AHCPR-funded research projects on cost, quality and access to health care, contact AHCPR Public Affairs at (301) 594-1364: Karen Migdail, ext. 1375; or Paula Zeller, ext. 1349.

Return to the AHCPR Press Release Index
Return to the AHCPR Home Page

New Consumer Materials Aid in the Effort to Reduce the Number of Babies Born with HIV

Press Release Date: Friday, Dec. 1, 1995

HHS Assistant Secretary for Health Philip R. Lee, M.D., today released new public information materials that will help pregnant women who have the human immunodeficiency virus (HIV) make informed decisions about medical interventions that can reduce mother to child (perinatal) transmission of HIV, the virus that causes Acquired Immunodeficiency Syndrome (AIDS).

In the United States alone, about 7,000 infants are born each year to HIV-positive women. As many as 2,000 of these infants will acquire the virus in utero, during childbirth or through breastfeeding. HIV/AIDS is the seventh leading cause of death in children 1-4 years of age and the fourth leading cause of death among women 25-44 years of age.

The new consumer information translates into lay language the results of a National Institutes of Health clinical trial known as the AIDS Clinical Trial Group (ACTG) 076, which showed that use of the antiretroviral drug zidovudine, commonly known as azidothymidine or AZT, reduced the rate of perinatal transmission of HIV by two-thirds.

The women in the study either were given AZT, or a placebo, beginning between 14 and 34 weeks gestation and continuing for the remainder of the pregnancy and delivery. For the first six weeks of life, AZT was also given to the babies of the women who received the drug. For children of women who did take AZT, the rate of perinatal transmission fell from one in four to one in twelve.

"The Clinton Administration is taking action to get this information into the hands of as many pregnant women with HIV as possible, along with what we know about the risks and benefits of AZT use during pregnancy," said Lee.

To that end, a public information campaign will target the population at greatest risk with a consumer brochure, posters, flyers, videotapes and audiotapes in English and Spanish; the brochure also is available in Haitian Creole.

The multi-media educational materials were developed by an Interagency Task Force within the Department of Health and Human Services, in collaboration with the Columbia University School of Public Health. The information in these materials is presented in a straightforward and objective manner, to help women weigh the risks and benefits of AZT therapy during pregnancy. To put a real-life face on the decision-making process, the materials include stories of women who have had to make this decision.

The educational materials will be distributed through federally-funded facilities, such as clinics and community health centers. In addition, HHS' Health Care Financing Administration today announced special joint efforts with four states to reach pregnant women with the information.

Information also can be obtained by calling the HIV/AIDS Treatment Information Service (ATIS), toll free, at 800-448-0440 or 800-243-7012 (TTY service for the deaf). Public service announcements in English and Spanish also will run on radio stations targeted to African-American and Hispanic audiences in the 40 cities with the highest prevalence of HIV infection in women, to enhance their access to this information.

"We encourage pregnant women who have HIV to get early prenatal care, talk to a health care provider, and get the facts about AZT," said Lee. "Ultimately, it is up to her to make an informed decision about what is best for herself and her baby."

For additional information contact, AHCPR Public Affairs at (301) 594-1364: Karen Migdail, ext.

1375; or Salina Prasad, ext. 1317.

Return to the AHCPR Press Release Index
Return to the AHCPR Home Page

Doctors' and Nurses' Knowledge and Attitudes

Colombotos, J., Messeri, P., McConnell, M.B., et al.: *Physicians, Nurses, and AIDS: Findings From a National Study*. Grant No. 5 R01 HS06359.

From a social perspective, AIDS (acquired immunodeficiency syndrome) revives longstanding issues about the relationships between health care professionals and their patients. A particular issue is the willingness of physicians and nurses to treat people with a contagious, fatal, and stigmatized disease. This report presents responses to AIDS-related questions from a national sample of 958 physicians and 1,520 registered nurses in 1990-91. Questions include willingness to treat AIDS patients and whether they believe that they are professionally obligated and should be legally required to do so, attitudes toward homosexual men and intravenous drug users, knowledge about HIV (human immunodeficiency virus) transmission, perceptions of the risk of HIV contagion, precautionary practices, trust in HIV authorities, career plans, and attitudes toward mandatory testing and mandatory reporting. Physicians' and nurses' responses are compared nationally. Comparisons are also made based on the AIDS prevalence in different parts of the country.

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Return to the AHCPR Home Page
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HIV/AIDS Research

Use of medicines other than ZDV to treat HIV infection has increased greatly over the past 5 years

Patients infected with the human immunodeficiency virus (HIV) that causes acquired immunodeficiency syndrome (AIDS) are no longer relying only on zidovudine (ZDV), the first antiretroviral licensed to treat AIDS (1987). Patients and their physicians are increasingly choosing treatments that combine ZDV with other retrovirals licensed since 1990: didanosine (ddI), zalcitabine (ddC), and stavudine (d4T); or they are using these newer antiretrovirals alone.

Researchers from The John Hopkins School of Public Health studied use of antiretroviral therapy in 1,129 HIV-infected homosexual and bisexual men in four cities who participated in a Multicenter AIDS Cohort Study (MACS). From 1990 to 1994, the proportion of men using ZDV monotherapy decreased from 27 percent to 17 percent (among men without an AIDS diagnosis) and from 60 percent to 17 percent (among men with an AIDS diagnosis). At the same time, the proportion of men using combination therapy increased from zero to 11 percent (without AIDS) and from 2 percent to 21 percent (with AIDS), and the proportion switching to a different monotherapy increased from zero to 8 percent (without AIDS) and from 8 percent to 26 percent (with AIDS).

Men without AIDS usually switched to combination therapy in response to declining CD4 lymphocyte counts or increased HIV symptoms (indications of drug failure). Men with AIDS usually switched to an alternative monotherapy. These choices reflect the current tendency of clinicians to use combination therapy for intermediate-stage HIV disease for its presumably stronger impact on sustaining CD4 count compared with monotherapy.

This research was supported by an intraagency agreement between the Agency for Health Care Policy and Research and the National Institute of Allergy and Infections Diseases (NIAID). More details are in "Factors associated with changes in the use of antiretroviral therapy by a cohort of homosexual men infected with the human immunodeficiency virus type I," by Lawrence P. Park, M.S.E., Neil M.H. Graham, M.D., Lisa P. Jacobson, Sc.D., and others, in *Clinical Infectious Diseases* 21, pp. 930-937, 1995.

Disadvantaged groups lag behind other patients in receipt of new HIV treatments

Innovative medical treatments often take longer to reach disadvantaged social groups. This was the case when zidovudine (ZDV), formerly known as AZT (azidothymidine), was first approved in 1987 to treat infection with the human immunodeficiency virus (HIV). HIV-infected blacks, women, and intravenous drug users (IDUs) who participated in New Jersey's Medicaid waiver program for HIV-infected persons (which paid for ZDV) were less likely to receive ZDV treatment than other program participants for the first 2 years after introduction of the treatment. However, by 1990 these groups received ZDV treatment and continued on the treatment at about the same rate as other Medicaid waiver patients.

Researchers in New Jersey, who were supported in part by the Agency for Health Care Policy and Research (HS06339), studied the use of ZDV among two groups of adults enrolled in New Jerseys Medicaid waiver program, those enrolling in 1987 and 1988 and those enrolling in 1989 and 1990. In the earlier group, only 45 percent of blacks vs. 63 percent of others had any use of ZDV, and ZDV use by women and IDUs was less likely to be sustained over time. For those taking ZDV, the proportion of time on the treatment was 41 percent for IDUs vs. 51 percent for others and 34 percent for women vs. 48 percent for men.

By 1989-1990, when ZDV use had become a more broadly applied standard of care for HIV-infected persons, there were no significant differences by race, sex, or risk group (for example, IDU or

homosexual) in receipt of ZDV (overall range of 65-71 percent), and differences in treatment persistence disappeared. The researchers conclude that differences in source of care (hospital clinic vs. private physician) probably contribute to socioeconomic differences in treatments received, especially for treatments that are new or require careful medical monitoring for success.

Details are in "The diffusion of innovation in AIDS treatment: Zidovudine use in two New Jersey cohorts," by Stephen Crystal, Ph.D., Usha Sambamoorthi, Ph.D., and Cheryl Merzel, Dr.P.H., in *Health Services Research* 30(4), pp. 593-614, 1995.

Voluntary HIV screening found to be cost-effective at some hospitals

Voluntary human immunodeficiency virus (HIV) screening of patients at hospitals where 1 percent of patients are typically infected with the virus is nearly as cost-effective as hypertension screening, according to a study supported by the Agency for Health Care Policy and Research (HS07273).

Routine voluntary HIV screening of inpatients and outpatients aged 15 to 54 years in high-prevalence hospitals has been recommended by the Centers for Disease Control and Prevention (CDC) but has not been widely adopted because of cost concerns. The recent study shows that this HIV screening program would identify about 110,000 undetected cases of HIV infection at a cost of $47,200 per year of life saved, which compares favorably with the $12,200 to $42,600 per year of life saved with hypertension screening.

The HIV screening program becomes even more cost-effective if individuals identified as HIV-infected respond to the test results by seeking appropriate medical care for their condition and by reducing high-risk sexual and other behaviors that may transmit HIV infection to others, notes lead investigator Douglas K. Owens, M.D., M.Sc. Dr. Owens and colleagues at the Veterans Affairs Palo Alto Health Care System and Stanford University Medical Center had previously found that a one-time national screening program to identify HIV-infected surgeons would be very costly, averaging $458,000 per year of life saved.

In this latest study, the researchers used a decision model to estimate the cost-effectiveness of the CDC-recommended screening program in acute care hospitals and associated clinics. Assuming that half of individuals identified as HIV-positive either declined to be treated or did not have access to medical care, the cost-effectiveness of the program would decline substantially from $47,200 per year of life saved to $59,600 per year of life saved. Assuming that a modest 15 percent of infected persons would change their behavior to reduce the risk of HIV transmission, the programs cost would decrease from $47,200 to $36,600 per year of life saved, an almost 25 percent improvement in cost-effectiveness. However, the researchers noted an important caveat: the effect of screening and early identification on quality of life is not well understood. If early identification decreases quality of life, the cost-effectiveness of a screening program declines from $47,200 per year of life saved to $92,400 per quality-adjusted year of life saved.

Details are in "Cost-effectiveness of HIV screening in acute-care settings," by Dr. Owens, Robert F. Nease, Jr., Ph.D., and Ryan A. Harris, M.S., in the February 26, 1996 Archives of Internal Medicine, pp. 394-404. For information about the earlier study, see "Screening surgeons for HIV infection: A cost-effectiveness analysis," by Dr. Owens, Ryan A. Harris, M.S., Patricia McJ. Scott, A.B., and Robert F. Nease, Jr., Ph.D., in the May 1995 *Annals of Internal Medicine* 122(9), pp. 641-652.

Rural AIDS cases have risen dramatically among some groups

Cases of acquired immunodeficiency syndrome (AIDS) among rural residents have risen dramatically in the past 5 years, especially among women, blacks, and adolescents. From 1991 to 1992 alone, rural AIDS cases increased at three times the rate of urban cases (9.4 vs. 3.1 percent). Until recently, many of these new cases were urban AIDS patients returning home in the last stages of their illnesses. However,

this group (made up mostly of homosexuals) is being replaced by locally infected persons who are more apt to be female and heterosexual, according to a study supported by the Agency for Health Care Policy and Research (282-93-0040).

Unfortunately, rural health care providers have limited resources and very limited experience in treating human immunodeficiency virus (HIV) infection and AIDS, explains Robin P. Graham, Ph.D., M.P.H., of the State University of New York at Buffalo, the study's lead investigator. An extensive review of the research literature by Dr. Graham and colleagues revealed that rural county AIDS cases increased more than five-fold between 1985 and 1991 in contrast to less than a two-fold increase in urban counties. Nearly one-third (30 percent) of rural HIV/AIDS cases were concentrated in the South Atlantic States.

Even after controlling for intravenous drug use, infection rates for rural black women were 20 times higher than for rural white women. Also, rural American Indian and Native Alaskan females had HIV infection rates comparable to their urban counterparts. In contrast to urban adolescents, rural female adolescents had infection rates nearly equal to those of rural males. Finally, rural groups at greatest risk for AIDS continue to be those least able to pay for care.

Details are in "HIV/AIDS in the rural United States: Epidemiology and health services delivery," Dr. Graham, Maureen L. Forrester, M.S., Jere A. Wysong, Ph.D., and others, in the December 1995 *Medical Care Research and Review* 52(4), pp. 435-452.

Return to the Research Activities Table of Contents
Return to the AHCPR Home Page

HIV/AIDS Research

Measuring a patient's viral load helps predict amount of time until HIV infection progresses to AIDS

The amount of time that it will take for patients infected with the human immunodeficiency virus (HIV) to develop AIDS can be predicted by the amount of viral RNA in their blood, according to a recent study that was supported in part by the Agency for Health Care Policy and Research (HS07782).

The investigators constructed a mathematical model to predict the time to symptomatic disease based on viral load measurements from longitudinal observations of untreated patients with asymptomatic HIV infection and CD4 cell counts greater than 500. For different viral loads, they calculated the time to progression to AIDS using a wide range of estimates for the time since seroconversion and the rate of change of viral load over time.

The investigators found that without antiretroviral treatment, asymptomatic HIV-infected patients with a viral load of 105 copies of viral RNA/ml serum are at risk of developing AIDS in less than 3 years, and patients with a viral load that is half a log higher (105.5) may develop AIDS in less than 1 year. In stark contrast, for patients with a viral load of 104.5, it may be at least 2 years or as many as 8 years before they develop AIDS; patients who have a viral load of 104 have 3 to 19 years before developing AIDS, according to the study.

Using viral load as a marker of disease status is important for guiding therapy during all stages of the disease, especially when the CD4 cell count, a marker of immune system deficiency, is maintained at levels close to normal (about 1,000). This is true even if the exact time of seroconversion (development of antibodies to HIV in the blood, the signal of infection) is unknown, points out Joseph Lau, M.D., of Tufts University School of Medicine. In patients with advanced stages of disease, CD4 cell counts may provide better information than viral load for long-term outcomes, but changes over time in viral load may be more useful in determining the efficacy of antiretroviral treatment, explains Dr. Lau.

For more information, see "Predictive value of viral load measurements in asymptomatic untreated HIV-1 infection: A mathematical model," by John P.A. Ioannidis, M.D., Joseph C. Cappelleri, Ph.D., M.P.H., Dr. Lau, and others, in *AIDS* 10(3), pp. 255-262, 1996.

Studies explore risk of opportunistic infections and risks and benefits of medications for HIV-infected patients

Patients infected with the human immunodeficiency virus (HIV) that causes AIDS are at risk for developing fungal and bacterial infections that take the "opportunity" provided by a patient's weakened immune systems to attack the body. For example, the incidence of bacterial pneumonia in patients with AIDS in San Francisco is 9.4 versus .07 per 1,000 person-years in non-HIV-infected persons of similar age. Also, oral and esophageal candidiasis, the most common opportunistic fungal infections in HIV-infected patients, have recently become resistant to previously effective fluconazole therapy. Finally, antiretroviral therapy to delay progression of HIV disease often causes toxicity leading to discontinuation of treatment, or as in the case of zidovudine, is only effective for 1 to 2 years. These issues are explored in the following four studies recently published by researchers supported in part by the Agency for Health Care Policy and Research (HS07809), and led by Richard D. Moore, M.D., M.H.Sc., of the Johns Hopkins University School of Medicine.

Gebo, K.A., Moore, R.D., Keruly, J.C., and Chaisson, R.E. (1996). "Risk factors for pneumococcal disease in human immuno-deficiency virus-infected patients," *The Journal of Infectious Diseases* 173, pp. 857-862.

From 5 to 20 percent of HIV-infected persons die from pneumonia. This study shows that HIV-infected

patients who are black, at an advanced stage of HIV infection (CD4 cell counts of 200 or less), and/or have a past history of pneumonia are at increased risk of developing pneumonia. Zidovudine treatment and pneumococcal polysaccharide vaccine given when the patient's CD4 cell count is 200 or more CD4 cells/mm3 (the patient is still capable of mounting an antibody response to the vaccine) seem to decrease this risk. The researchers studied patients at an HIV clinic who had pneumonia between January 1990 and July 1994 and compared them with HIV-infected persons who were not treated for pneumonia. Results showed that patients who developed pneumonia were nearly four times more likely to be black than controls, over three times as likely to have less than 200 CD4 cells/mm3, three times more apt to have a history of pneumonia, and six times as likely to have an albumin level of less than 3 g/dL. Patients who developed pneumonia also were less likely to have used zidovudine and pneumonia vaccine when they had CD4 cell counts higher than 200.

Maenza, J., Keruly, J.C., Moore, R.D., and others. (1996, January). "Risk factors for fluconazole-resistant candidiasis in human immunodeficiency virus-infected patients," *The Journal of Infectious Diseases* 173, pp. 219-225.

There have been increasing reports of HIV-infected patients developing oral or esophageal candidiasis that is resistant to therapy with fluconazole. This study shows that advanced immunosuppression, indicated by low CD4 cell count, and increased exposure to oral azole medications increase the risk for developing fluconazole resistance. The researchers conducted a case control study to identify risk factors for development of this resistance in 25 patients with fluconazole-resistant candidiasis, whom they compared with controls who had treatment-responsive candidiasis. After their first episode of candidiasis, patients who later developed fluconazole resistance had more treated episodes than did matched controls (3.1 vs. 1.8) lower median CD4 cell counts (11 vs. 77/mm3), and greater median durations of all antifungal therapy (419 vs. 118 days) and systemic azole therapy (272 vs. 14 days). These findings raise the question of whether oropharyngeal candidiasis should be treated with topical agents whenever possible, reserving systemic azoles for patients with esophageal candidiasis or invasive mycoses, conclude the researchers.

Moore, R.D., Fortgang, I., Keruly, J., and Chaisson, R.E. (1996, July). "Adverse events from drug therapy for human immuno-deficiency virus disease." *American Journal of Medicine* 101 (7) pp. 34-48.

Adverse reactions to antiretroviral drugs and drugs that prevent *Pneumocystis carinii* pneumonia (PCP) in patients infected with HIV are common, but serious reactions requiring hospitalization are rare. These adverse reactions increase progressively as CD4 cell count declines, and they vary according to the sex and race of the patient, according to these researchers. They calculated the number of adverse reactions from use of zidovudine, didanosine, zalcitabine, cotrimoxazole, and dapsone in 1,450 urban, HIV-infected patients whose CD4 cell counts were 500 cells/mm3 or less. Overall adverse reactions were 16.2 per 100 person-years (PY) for dapsone; 24.1 per 100 PY for didanosine; 26.3 per 100 PY for zidovudine; 26.3 per 100 PY for cotrimoxazole; and 37 per 100 PY for zalcitabine. The adverse reactions increased significantly with a decline in CD4 cell count from more than 200 to less than 100 cells/mm3 for all drugs but dapsone. Women were more likely than men to have a bad reaction from didanosine and from cotrimoxazole. White patients were nearly twice as likely as black patients to have an adverse reaction to cotrimoxazole. Only 6 percent of all adverse reactions required hospitalization, and there were no deaths.

Moore, R.D., Keruly, J.C., and Chaisson, R.E. (1996, May). "Duration of the survival benefit of zidovudine therapy in HIV infection." *Archives of Internal Medicine* 156, pp. 1073-1077.

The ability of zidovudine (ZDV) therapy to prolong survival in HIV-infected patients is limited to between 1 and 2 years in patients with CD4 cell counts of 500/mm3 or less, perhaps due to the emergence of ZDV-resistant HIV. Beyond 1 year of ZDV use, changing to an alternative therapy—such as didanosine, zalcitabine, stavudine, or combination therapy—may be appropriate, conclude the authors. They determined the duration of ZDV benefit in 393 patients who were receiving HIV care at a large urban clinic; 57 percent of the patients were injecting drug users. They compared the 235 patients who used ZDV with the 158 nonusers and found that the risk of dying was reduced by two-thirds when

ZDV was used for less than a year. However, this hazard declined only 25 percent by the second year. These findings demonstrate an early, though limited, benefit of ZDV in an urban, predominantly black population with a relatively high proportion of women and injecting drug users. This study preceeded current work on combination therapies and contributed to the evolving knowledge base on treatment options for HIV-infected patients.

Return to *Research Activities* Table of Contents
Return to AHCPR Home Page

HIV/AIDS Research

Preventive therapies delay the onset of some opportunistic diseases in HIV patients

Opportunistic diseases are common complications of HIV infection, but the incidence rates of secondary *Pneumocystis carinii* pneumonia (PCP), cryptococcal meningitis, and herpes zoster have declined in the past 5 years, and they are being diagnosed at a later stage of HIV disease (lower median CD4 cell count). In addition, the incidence rates of primary PCP and Kaposi sarcoma also appear to be declining compared with historical estimates.

These improvements are due to the effective use of antiretroviral therapy, targeted preventive therapy, and more comprehensive clinical management of the disease, according to a study supported by the Agency for Health Care Policy and Research through its pharmaceutical outcomes research program (HS07809). The study was led by Johns Hopkins University School of Medicine researchers, Richard D. Moore, M.D., M.H.Sc., and Richard E. Chaisson, M.D.

They estimated the probability of developing opportunistic infection and cancer, measured the number of CD4 cells at the time opportunistic disease developed and survival after its onset, and examined the association between preventive drug therapies and occurrence of opportunistic infection among 1,246 HIV-infected patients with CD4 counts of 300 or less (normal count is about 1,000) at an urban university HIV clinic from 1989 to 1995. Between the earlier period (1989-1992) and the later period (1993-1995), the incidence of several opportunistic infections decreased: cryptococcal meningitis declined from 3 to 1.4 events per 100 person-years; second-time PCP declined from 6.2 to 3.7; and herpes zoster declined from 4.2 to 2.4.

In the late 1980s, opportunistic infections typically began to appear when an HIV-infected person's CD4 lymphocyte count dropped to about 200. In this study, only infections with herpes simplex virus, tuberculosis, and herpes zoster occurred at CD4 counts greater than 100. Toxoplasmosis, progressive multifocal leukoencephalopathy, the wasting syndrome, second-time PCP, cytomegalovirus infection, and *Mycobacterium avium* complex bacteremia occurred at a mean CD4 count of less than 50. After adjustment for CD4 count, the use of fluconazole was associated with a decreased rate of cryptococcal meningitis and candidiasis, rifabutin use with a decreased rate of *M. avium* complex bacteremia, and trimethoprim-sulfamethoxazole use with a decreased rate of secondary PCP.

For more information, see "Natural history of opportunistic disease in an HIV-infected urban clinical cohort," by Drs. Moore and Chaisson, in the April 1, 1996 *Annals of Internal Medicine* 124(7), pp. 633-642.

Return to the Research Activities Table of Contents
Return to the AHCPR Home Page

HIV/AIDS Research

Course of HIV infection not related to sex, race, drug use, or socioeconomic status

How quickly persons infected with the human immunodeficiency virus (HIV) progress to full-blown AIDS (acquired immunodeficiency syndrome) and how long they survive are not related to sex, race, injection drug use, or socioeconomic status. Rather, HIV disease progression depends on CD4 cell count, receipt of antiretroviral therapy, and age, according to a study supported by the Agency for Health Care Policy and Research (HS07809).

The study showed that HIV-infected persons were twice as likely to progress to AIDS or die from their infection if they had a low CD4 cell count (201 to 350 cells compared with a normal cell count of about 1,000) and were symptomatic at study enrollment. They had nearly twice the risk (1.7) if they had received antiretroviral therapy prior to study enrollment (when the 1-2 year survival benefit of the therapy would already be partially exhausted), and an increased risk of 2 percentage points per year of age. These results provide strong evidence that the faster disease progression and shorter survival observed among women and blacks, for example, are likely the result of inadequate medical care rather than biologic differences among groups in the natural history of HIV infection, explains Richard E. Chaisson, M.D., of Johns Hopkins University School of Medicine, who led the study.

The researchers measured disease progression and survival in a group of 1,372 HIV-seropositive patients treated at a single urban center and followed for a median of 1.6 years. They found that CD4 cell count was the most important predictor of survival. There were no significant differences in survival between men and women, blacks and whites, drug users and non-drug users, or patients with different median annual incomes. Use of prophylaxis against *Pneumocystis carinii* pneumonia and zidovudine (ZDV) use after study enrollment (when survival benefits can be fully reaped) were associated with a significantly decreased risk of death.

Details are in "Race, sex, drug use, and progression of human immunodeficiency virus disease," by Dr. Chaisson, Jeanne C. Keruly, B.S.N., and Richard D. Moore, M.D., M.Sc., in the September 21, 1995 *New England Journal of Medicine* 333(12), pp. 751-756.

Researchers examine health care use and outcomes among HIV-infected women

AIDS (acquired immunodeficiency syndrome), the end stage of infection with the human immunodeficiency virus (HIV), is increasing among women at an alarming rate. By the end of June 1995, more than 68,000 cases of AIDS among women had been reported to the Centers for Disease Control and Prevention. Cases of AIDS in women have been reported in every State, and AIDS is now the leading cause of death among black women 25 to 44 years of age in New York State and New Jersey.

Despite the growing number of women infected with HIV, knowledge of their use of health care resources and methods of financing their care is surprisingly limited. In a recent study, investigators in the Center for Delivery Systems Research, Agency for Health Care Policy and Research, compared inpatient mortality and resource use for hospitalizations of women infected with HIV with those of HIV-infected males and a random sample of non-HIV-infected females from the same time period (October 1, 1986 through December 31, 1987). Data for this analysis were obtained from the large sample of hospitals participating in the Hospital Cost and Utilization Project, 1980-87 (HCUP-2).

Few differences in resource use and outcomes were found between HIV-infected women and men. However, the expected source of payment for inpatient stays differed significantly by sex, with inpatient stays of HIV-infected men more often indicating some form of private insurance, and inpatient care for

HIV-infected women disproportionately financed through public sources.

Differences in resource use and outcomes between HIV-infected women and a random sample of discharges of non-HIV-infected women were striking. HIV-infected women had longer average lengths of stay and higher total hospital charges. Among women hospitalized for deliveries, the average length of stay, total charges, and charges per day were significantly higher for HIV-positive women than for women in the random sample.

Inpatient care for PCP varies according to insurance status and hospital characteristics

Racial factors do not appear to be an important determinant of the intensity of diagnostic or therapeutic care among patients who are hospitalized with *Pneumocystis carinii* pneumonia (PCP). Rather, variations in care for human immunodeficiency virus (HIV)-related PCP are largely due to differences in patients' health insurance and the characteristics of the admitting hospital, according to a study supported in part by the Agency for Health Care Policy and Research (HS06494 and HS07846) and the Department of Veterans Affairs (VA). This study is the first to evaluate variations in care along racial lines for persons with PCP.

The research team, led by Charles L. Bennett, M.D., of Northwestern University and the Lakeside VA Medical Center, and Susan E. Cohn, M.D., M.P.H., of Rochester University, reviewed the charts of 627 VA patients and 1,547 non-VA patients with suspected or confirmed PCP, who were hospitalized from 1987 to 1990. At VA hospitals, where financial barriers to care are minimal, in-hospital mortality rates, use and timing of bronchoscopy (used to distinguish PCP from other respiratory problems such as tuberculosis), and receipt of timely anti-PCP medications were not significantly different for white, black, and Hispanic patients with PCP. Among non-VA patients, black and Hispanic patients were more likely to die in the hospital and less likely to undergo a diagnostic bronchoscopy in the first 2 days of hospitalization.

These racial differences in mortality and use of bronchoscopy were almost entirely accounted for by differences in health insurance and hospital characteristics. Having Medicaid insurance and receiving care at county and State hospitals were the major factors associated with patients not undergoing a bronchoscopy.

The investigators point out that physicians receive lower reimbursement for bronchoscopies under Medicaid than under private insurance, raising the possibility that quality of care is sensitive to level of physician payments. They add the caution, however, that the possibility that Medicaid patients choose not to have the procedures cannot be excluded. Further, they note that national policies which lead to more uniform health insurance programs are needed for persons with HIV and AIDS (acquired immunodeficiency syndrome).

Details are in "Racial differences in care among hospitalized patients with *Pneumocystis carinii* pneumonia in Chicago, New York, Los Angeles, Miami, and Raleigh-Durham," by Drs. Bennett and Cohn, Ronnie D. Horner, Ph.D., and others, in the August 7/21, 1995 issue of the *Archives of Internal Medicine* 155, pp. 1586-1592.

Publicly insured, HIV-infected patients are much less likely to undergo bronchoscopy to confirm PCP

A new study shows that publicly insured patients infected with the human immunodeficiency virus (HIV) were only half as likely to receive bronchoscopies to confirm diagnosis of *Pneumocystis carinii* pneumonia (PCP) as their privately insured counterparts. On the other hand, health insurance status did not affect the likelihood of these patients being offered antiretroviral therapy or of receiving aerosolized pentamidine to prevent PCP in the 6 months prior to their first PCP episode.

PCP, which is the most common HIV-related infection, often signals the onset of acquired immunodeficiency syndrome (AIDS). As such, it sometimes results in eligibility for Social Security disability and Medicaid benefits. Early diagnosis of PCP by bronchoscopy could mean the difference between a short-lived, mild disease and a fatal one, according to the researchers, who were supported in part by the Agency for Health Care Policy and Research (HS06211).

Using administrative discharge records and outpatient databases, the researchers studied 450 HIV-infected patients, mostly young, white, homosexual men, who experienced their first episode of PCP at a large California medical facility. After adjusting for differences in patient race, age, HIV severity, and mode of HIV transmission (for example, homosexual liaison or injection drug use), the researchers found that patients with public insurance were half as likely as privately insured patients to receive bronchoscopy. The reasons for this difference are unclear, according to the researchers, who note that insurers' requirements for laboratory confirmation of PCP may differ, a physician may decide to treat patients for PCP based on symptoms alone without laboratory confirmation, and some patients may refuse bronchoscopy.

Details are in "Health insurance and utilization in *Pneumocystis carinii* pneumonia," by Sana Loue, J.D., Ph.D., Donald J. Slymen, Ph.D., Hal Morgenstern, Ph.D., and Christopher Whalen, M.D., M.S., in the *Journal of General Internal Medicine* 10, pp. 461-463, 1995.

Recent studies question readiness of primary care physicians to care for HIV-infected patients

Primary care physicians are providing care for a growing number of persons infected with the human immunodeficiency virus (HIV), yet in some instances, this care may be inadequate, according to two recent studies supported by the Agency for Health Care Policy and Research (HS06454). This is unfortunate, since early primary care interventions have the potential to enhance patients' quality of life and minimize or prevent HIV-related complications such as *Pneumocystis carinii* pneumonia (PCP) and tuberculosis (TB), explains Paul G. Ramsey, M.D., of the University of Washington.

In the first study, a standardized patient (SP) was trained to portray a person diagnosed with HIV infection but not yet symptomatic who is seeking a primary care physician. The researchers evaluated 121 primary care physicians' abilities to assess these SPs. Only a minority of physicians recommended standard primary care screening tests and vaccinations for HIV-infected persons, including viral hepatitis screening (35 percent), syphilis serologic testing (32 percent), and pneumococcal vaccination (23 percent). Although most physicians (87 percent) indicated they would obtain CD4 cell counts (a marker of HIV disease progression), only 50 percent indicated they would start therapy to prevent PCP, a potentially life-threatening HIV-related infection. Only 53 percent of physicians recommended isoniazid therapy to prevent the development of active TB infection in patients with documented positive TB tests. Performance on each of these tasks improved with physician HIV experience. Since these studies were carried out in 1992, it is likely that many primary care physicians now have additional experience in caring for HIV patients.

In the second study, 134 primary care physicians saw an SP with an unidentified HIV infection and classic PCP symptoms, such as frequent cough and dizziness on exertion, and chest radiograph and arterial blood gas results indicating PCP. Early diagnosis and treatment can make a critical difference between PCP being a mild and relatively brief illness and one resulting in respiratory failure and death. Yet the results showed significant delay in PCP diagnosis and treatment. About 77 percent of the physicians included PCP in their differential diagnoses, and 71 percent identified the SP's HIV risk. Yet only 47 percent of physicians ordered a diagnostic test for PCP, only 12 percent prescribed an adequate dose of trimethoprim-sulfamethoxazole to treat PCP, and just 6 percent initiated adjunctive prednisone therapy, even though prednisone was indicated by the blood gas result.

For more details, see "Physicians' ability to provide initial primary care to an HIV-infected patient," by J. Randall Curtis, M.D., M.P.H., Douglas S. Paauw, M.D., Marjorie D. Wenrich, M.P.H., and others, in the August 7/21, 1995 issue of the *Archives of Internal Medicine* 155, pp. 1613-1618, and "Ability of

primary care physicians to diagnose and manage *Pneumocystis carinii* pneumonia," by the same authors, in the *Journal of General Internal Medicine* 10, pp. 395-399, 1995.

In rating doctors, teens express special concerns about HIV transmission and confidentiality

Good infection control procedures, competency, respect for confidentiality, and good interpersonal skills, such as honesty and the ability to relate to teenagers, top the list of physician qualities teenagers value, according to a recent study. In fact, when asked to complete a questionnaire, Philadelphia 9th graders listed four of the top ten desirable physician characteristics as pertinent to infection control: physician hand washing, use of clean instruments, physician and site cleanliness, and physician seronegativity for the human immunodeficiency virus (HIV).

Concerns about infection control stemmed primarily from the adolescents' fears about becoming infected with HIV from the health care provider, an occurrence whose rarity was probably masked by the intense media coverage surrounding the case of a young woman who became HIV-infected through her dentist. These fears apparently overshadowed all other HIV education efforts in Philadelphia at the time, explains Gail B. Slap, M.D., M.S., of the University of Pennsylvania's School of Medicine, whose research was supported in part by the Agency for Health Care Policy and Research (HS07876).

Dr. Slap and her colleagues used a questionnaire to ask 6,821 Philadelphia 9th graders about characteristics of health care providers and sites that affect their decision to seek health care. The questionnaire was based on focus groups where teenagers generated a prioritized list, rather than on investigators' concepts of what would be important to teens. Six of the top items identified by teens pertained to providers' interpersonal characteristics. Specific health care site, services, or outreach programs were less important. The researchers conclude that health care providers should wash their hands in front of adolescents to allay fears of disease transmission, educate teens about their right to confidential health care, and explain how to gain access to needed care.

For more details, see "Adolescents' perceptions of factors affecting their decisions to seek health care," by Kenneth R. Ginsburg, M.D., M.S.Ed., Dr. Slap, Avital Cnaan, Ph.D., and others, in the *Journal of the American Medical Association* 273(24), pp. 1913-1918, 1995.

Return to the Research Activities Table of Contents
Return to the AHCPR Home Page

HIV/AIDS Research

Primary care physicians often fail to recognize important signs of HIV infection

Practicing primary care physicians may miss important signs of infection with the human immunodeficiency virus (HIV) during patient examinations, according to a study supported by the Agency for Health Care Policy and Research (HS06454). Even when directed by the patient to sites of symptoms typical of HIV disease, only about 25 percent of primary care physicians both detected the abnormality and correctly diagnosed the condition.

Prior studies have documented inadequate skills associated with assessment of risk for HIV infection. This is the first published study of physicians' ability to identify physical findings associated with HIV infection.

In this study, only about 26 percent of physicians evaluating a patient with Kaposi's sarcoma (KS)—with classic raised, reddish-purple KS lesions and associated pain—were able to detect and correctly diagnose the KS. KS is a rare tumor in individuals not infected with HIV and the most common tumor in patients who are HIV-positive. Less than 23 percent of physicians evaluating a patient with oral hairy leukoplakia (OHL), with sore throat and white spots on the tongue, detected the spots and correctly diagnosed the OHL, which is strongly associated with HIV infection. Finally, only 17 percent of physicians detected diffuse lymph-adenopathy in a patient complaining of fatigue, fever, and joint pain. Although associated with many diseases, diffuse lymphadenopathy is a common finding in HIV-positive individuals.

Physician deficiencies in HIV-related physical diagnosis skills did not appear to be associated with year of graduation from medical school or type of residency training, suggesting the need for additional educational interventions to improve these skills. Such oversights are a concern, especially when one considers that preventable serious infections and premature deaths occur in individuals with undiagnosed HIV infection, according to researchers at the University of Washington School of Medicine, Seattle.

The investigators assessed the ability of 134 primary care physicians (general internists and family practitioners) to identify these three symptoms of HIV infection during examination of a standardized patient (SP). SPs are individuals with prominent physical findings who are trained to enact a specific case presentation and to evaluate physicians' performance.

Details are in "Ability of primary care physicians to recognize physical findings associated with HIV infection," by Douglas S. Paauw, M.D., Marjorie D. Wenrich, M.P.H., J. Randall Curtis, M.D., M.P.H., and others, in the November 1, 1995 *Journal of the American Medical Association* 274(17), pp. 1380-1382.

Even when health status is very poor, most AIDS patients want to be revived if their hearts stop

For persons with acquired immunodeficiency syndrome (AIDS), current health status does not necessarily affect their desire to be revived if their hearts stop, according to a study supported by the Agency for Health Care Policy and Research (HS06239).

About 65 percent of terminally ill AIDS patients in this study, mostly young homosexual and bisexual men, wanted to be revived if their hearts stopped. Overall, those who considered themselves to be in the best health were more likely to want to be revived. However, over half of those who considered their health to be the very worst (the lowest quartile) also wanted to be resuscitated.

A key finding was that the relationship between health status and desire for resuscitation does not hold

up for all patients. For the third of patients who expressed the most reluctance to give up life, by saying they wanted life extension even if it meant living in some undesirable state (such as being blind or fed by a tube), current health status was unrelated to desire for resuscitation.

These results suggest limits to the validity of assessing how a patient values his or her current health status by asking questions that involve loss or risk of life, such as "standard gambles" (for example, what risk the patient is willing to take of dying in surgery to cure a health problem) and time trade-off questions (for example, how many years of later life a person is willing to give up for better life now). A general reluctance to give up life may confound how patients answer such questions, notes Arnold Epstein, M.D., of Harvard Medical School. These findings are based on interviews of 291 patients with AIDS, who participated in the Boston Health Study during 1990 and 1991.

For more information, see "The role of reluctance to give up life in the measurement of the values of health states," by Floyd J. Fowler, Jr., Ph.D., Paul D. Cleary, Ph.D., Michael P. Massagli, Ph.D., and others, in *Medical Decision Making* 15(3), pp. 195-200, 1995.

Hospitalization costs rise sharply for AIDS patients in the months prior to death

A high proportion of the total cost for treating acquired immunodeficiency syndrome (AIDS) is concentrated in the last few months before patient death. Hospitalization costs rise sharply during that time, while outpatient costs drop slightly, according to a recent study. If costly inpatient episodes prior to death are typical, any cost savings achieved by growing efforts to expand community-based AIDS care may be minimized, notes John A. Fleishman, Ph.D., of the Center for Cost and Financing, Agency for Health Care Policy and Research.

He and Brown University researchers analyzed hospital medical and billing records for 914 people with AIDS who were receiving health services in nine cities across the United States in 1990-1991 and whose usual source of care was a hospital clinic. During the 18-month study period, the number of inpatient admissions was four times as high for AIDS patients who died, and the number of inpatient nights was more than six times higher than those of AIDS patients who did not die, regardless of patient race, exposure group, community, insurance status, or disease stage.

As a result, annualized inpatient costs for AIDS patients who died were seven times greater than costs for patients who did not die. For example, among 69 decedents for whom four quarters of billing data were available, quarterly inpatient costs during the year prior to death were $3,109 (at 1 year prior to death), $3,511 (at 9 months prior to death), $5,362 (at 6 months prior to death), and $17,940 (during the last 3 months of life) compared with the respective costs for 69 nondecedents of $775, $853, $988, and $1,039. In contrast, mean outpatient costs displayed no systematic trend over time. Although total terminal AIDS care costs for whites did not differ from blacks, whites had higher outpatient use and lower inpatient use than minority patients.

Further details are in "Longitudinal patterns of medical service use and costs among people with AIDS," by Dr. Fleishman, Vincent Mor, Ph.D., and Linda L. Laliberte, M.S., J.D., in HSR: *Health Services Research* 30(3), pp. 403-424, 1995.

Return to the Research Activities Table of Contents
Return to the AHCPR Home Page

HIV/AIDS Research

Trimethoprim-sulfamethoxazole continues to be the best choice for preventing PCP in AIDS patients

Pneumocystis carinii pneumonia (PCP) remains one of the most common life-threatening complications of AIDS. Of the three regimens most often used for PCP prophylaxis, trimethoprim-sulfamethoxazole (TMP-SMX) is superior to prevent initial and second-time PCP (primary and secondary prophylaxis) and most cost-effective for secondary prophylaxis, according to two studies supported in part by the Agency for Health Care Policy and Research (HS07782 and HS06694).

A meta-analysis of 35 randomized trials (conducted between 1991 and 1995 and involving 6,583 patients) led by Joseph Lau, M.D., of New England Medical Center Hospitals, compared three different treatment regimens: TMP-SMX, dapsone, (both are oral medications), and aerosolized pentamidine (AP) with each other or placebo. AP was well tolerated regardless of the dose used (usual recommended dose is 300 mg per month via nebulizer), but prophylaxis failure might be halved if the dose were doubled. Oral medications were five times more likely than AP to be discontinued because of toxic reactions.

Regardless of dose, TMP-SMX was almost universally effective for patients who tolerated it. The risk of discontinuation because of side effects decreased 43 percent if one double-strength tablet (160 mg TMP, 800 mg SMX) was given three times per week instead of daily (usual recommended dose). For dapsone, in 100 patients given 100 mg per day instead of twice per week for 1 year (primary prophylaxis), 7 fewer patients would develop PCP, but 17 more would have significant toxic reactions.

The second study shows that TMP-SMX also is more cost-effective than AP for preventing recurring PCP. Investigators at Dartmouth Medical School developed a model of secondary PCP prophylaxis based on the medical literature and then used efficacy and toxicity data from a controlled clinical trial to validate the model. They compared three clinical strategies in a hypothetical group of patients who had completed 21 days of therapy for PCP: no prophylaxis (control group), prophylaxis with TMP-SMX (one double-strength tablet per day), and prophylaxis with AP (300 mg per month).

In the literature-based model, yearly prophylaxis costs for TMP-SMX and AP were $468 and $1,577, respectively. Assuming equal efficacy for the two agents, the incremental cost-effectiveness ratio for TMP-SMX was $350 compared with no prophylaxis; for AP it was $110,880 compared with TMP-SMX, since AP was associated with only a minimal increase in life expectancy and a substantial increase in cost. Data from the randomized trial indicated annual costs of $656 per person for TMP-SMX and $1,573 per person for AP. This translates into annual savings of over $17.4 million for the 19,039 patients newly diagnosed as having PCP in 1993, if they were started on TMP-SMX rather than AP to prevent reinfection with PCP.

More details of the first study are in "Meta-analysis of the relative efficacy and toxicity of *Pneumocystis carinii* prophylactic regimens," by John P. Ioannidis, M.D., Joseph C. Cappeleri, Ph.D., M.P.H., Paul R. Skolnik, M.D., and others, in the January 22, 1996 *Archives of Internal Medicine* 156, pp. 177-188. For the second study, see "Validating literature-based models with direct clinical trial results," by Kenneth A Freedberg, M.D., M.Sc., W. David Hardy, M.D., Robert S. Holzman, M.D., and others, in the January 1996 issue of *Medical Decision Making* 16(1), pp. 29-35.

Return to the Research Activities Table of Contents
Return to the AHCPR Home Page

http://www.ahcpr.gov/research/nov96/ra2.htm#head10

also had similar, but ubstantially lower, access to personal physicians (33 percent and 40 percent, respectively).

The finding that poor Mexican Americans with health insurance did use the health services available demonstrates that health care access may improve health care outcomes for Mexican Americans. But more comprehensive community-based campaigns to promote health and better use of health services among underprivileged groups should be developed, urge the researchers.

More details are in "Health care access among Mexican Americans with different health insurance coverage," by Robert P. Trevino, M.D., Fernando M. Trevino, Ph.D., M.P.H., Rolando Medina, M.D., M.P.H., and others, in the *Journal of Health Care for the Poor and Underserved* 7(2), pp. 112-121, 1996.

Return to Table of Contents

HIV/AIDS Research

Symptoms such as fatigue and fever serve as a barometer of physical functioning in AIDS patients

Symptoms such as fatigue, fever, and neurologic problems are a better guide to the physical functioning of AIDS patients than biologic and physiologic factors such as current infections or time since diagnosis. These symptoms explain more than half of how well a patient with AIDS is functioning. Adding biologic and physiologic factors only explains 2 percent more of the differences in patients' physical functioning, according to a study supported by the Agency for Health Care Policy and Research (HS06239).

Biologic and physiologic variables such as weight loss, lower hemoglobin level, current non-pneumonia bacterial infections, Mycobacterium avium complex infection, oral Pneumocystis carinii pneumonia (PCP) prophylaxis, and cigarette smoking were associated with worse physical functioning. Use of zidovudine (ZDV) was associated with better physical functioning. These factors explained 29 percent of variation in physical functioning among patients.

However, symptoms alone explained nearly twice (56 percent) the variation. In each case, better mental health was associated with fewer symptoms. Lower total white blood cell count, longer time since diagnosis, weight loss in the last year, and more episodes of PCP were all associated with more fatigue. Weight loss and asthma were associated with more neurologic symptoms, and ZDV use in the last month was associated with fewer neurologic symptoms. This analysis by Massachusetts researchers was based on a conceptual model which proposed that symptoms mediate the relation between biologic and physiologic variables and physical functioning. The researchers used the model, patient interviews, and medical chart reviews to predict physical functioning in 305 persons with AIDS from three sites in Boston.

The researchers point out several limitations to their work. First, as with all cross-sectional data, the direction of causal effects could not be determined. Second, only one measure of health-related quality of life—physical functioning—was examined, and these findings do not necessarily apply to other measures. Third, too few patients had current CD4 cell counts, so this important variable could not be included. Fourth, there are limitations related to the size of the study and the constraints of a natural experiment in which data were limited to what physicians decided to order in the course of routine clinical care. And finally, although the researchers enrolled a sociodemographically diverse population, there is no way to know if these findings also apply to other groups of persons with AIDS, such as women. The researchers also point out that although oral PCP prophylaxis was associated with worse physical functioning, when the number of PCP episodes was added to the model, oral PCP prophylaxis

http://www.ahcpr.gov/research/nov96/ra2.htm#head10

was no longer significant. For more information, see "Clinical predictors of functioning in persons with acquired immunodeficiency syndrome," by Ira B. Wilson, M.D., M.Sc., and Paul D. Cleary, Ph.D., in the June 1996 issue of *Medical Care* 34(6), pp. 610-623.

Return to Table of Contents

AHCPR News and Notes

Ten new members have been appointed to the National Advisory Council

Ten new members have been appointed to the National Advisory Council for Health Care Policy, Research, and Evaluation, and the term of service of the council's Chairman, Walter J. McNerney, M.H.A., has been extended to May 1997. The council, which comprises 17 private-sector health care experts and consumers and 7 top Federal health officials, advises the Secretary of the Department of Health and Human Services and the Administrator of the Agency for Health Care Policy and Research on matters elating to AHCPR's activities to enhance the quality, appropriateness, and effectiveness of health care services and access to such services.

The 10 new members of the council are:

- Richard E. Behrman, M.D., J.D, Managing Director, Center for the Future of Children, The David and Lucile Packard Foundation, Los Altos, CA
- Nancy Wilson Dickey, M.D., Chair, Board of Trustees, American Medical Association, and Program Director, Family Practice Residency Department of the Brazos Valley, and Associate Professor, Department of Family and Community Medicine, Texas A&M University, College Station, TX
- Jose Julio Escarce, M.D., Ph.D., Senior Fellow, Leonard Davis Institute and Assistant Professor, School of Medicine, University of Pennsylvania, Philadelphia, PA
- Sharon C. Kiely, M.D., Director of Health Services, Primary Care Health Services, Inc., Pittsburgh, PA
- Ada Sue Hinshaw, Dean and Professor, University of Michigan School of Nursing, Ann Arbor, MI
- Jeffrey P. Koplan, M.D., M.P.H., President, The Prudential Center for Health Care Research, Atlanta, GA
- Woodrow Meyers, Jr., M.D., M.B.A., Director, Health Care Management, Ford Motor Company, Dearborn, MI
- Martin Paris, M.D., M.P.H., Vice President, Medical Affairs, Tenet Healthcare Corp., Dallas, TX
- Stephen M. Shortell, Ph.D., A.C. Buehler Distinguished Professor of Health Services Management, J.L. Kellogg Graduate School of Management, Northwestern University, Evanston, IL
- W. Leigh Thompson, M.D., Ph.D., Chairman, Profound Quality Resources, Ltd., Charleston, SC

They will join six existing council members whose 3-year terms will expire in May 1997. In addition to Walter McNerney, the returning members of the panel are:

- Helen Darling, M.A., Manager, Health Strategy and Programs, Corporate Benefits, Xerox Corporation, Stamford, CT
- Robert M. Krughoff, J.D., President, Center for the Study of Services, Washington, DC
- W. David Leak, M.D., Medical Director, Pain Control Consultants, Columbus, OH
- Harold S. Luft, Ph.D., Director, Institute for Policy Studies, School of Medicine, University of California, San Francisco, CA
- Edward B. Perrin, Ph.D., Professor, Department of Health Services, School of Public Health,

Health Insurance Coverage

Schur, C.L., and Berk, M.L.: Health Insurance Coverage of Persons With HIV-Related Illness: Data From the ACSUS Screener. *AIDS Cost and Services Utilization Survey (ACSUS) Report*, No. 2. AHCPR Pub. No. 94-0009. Rockville, MD: Agency for Health Care Policy and Research, 1994.

The AIDS Cost and Services Utilization Survey (ACSUS) is a longitudinal study of persons with HIV-related disease. It is the largest data collection effort targeting the population of persons infected with HIV. In a combination of personal interviews and abstraction of medical and billing records spanning an 18-month period, information is collected on more than 1,900 HIV-infected adults and adolescents, including approximately 350 women, and on 140 HIV-infected children under 13 years of age. This report deals with health coverage of HIV-positive persons. Coverage, categorized as private, public, or none, is discussed separately for each of three stage-of-illness groups: asymptomatic, HIV-positive; symptomatic, non-AIDS; and AIDS. Data are also examined in terms of respondents' race or ethnicity, gender, and exposure route.

Overall, 53 percent of respondents reported public coverage for their medical care. Another 28 percent were covered by private insurance, and 19 percent had no source of payment other than themselves or their family. Public coverage rose from 37 percent for asymptomatic persons to 50 percent for those who were symptomatic but non-AIDS to 62 percent for persons with AIDS.

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Return to the AHCPR Home Page
Department of Health and Human Services Home Page

Highlights from Recent AHCPR Research Findings

Media Advisory Date: October 8, 1996

The Agency for Health Care Policy and Research (AHCPR) works to improve the quality of health care, reduce costs, and broaden access to essential services. Here are some of the findings described in the July/August, 1996, issue of AHCPR's *Research Activities*.

Rural Hospital Downsizing Failed to Improve Financial Performance

Rural hospitals that downsized in an attempt to improve financial performance in the 1980s did not succeed in their efforts, according to a study conducted by University of Michigan researchers. About 15 percent of rural hospitals downsized during the mid and late 1980s by selling, shutting down, or restructuring ownership of a hospital unit or service. However, these hospitals did not perform any better financially than hospitals that did not downsize.

Stephen S. Mick, Ph.D., and Christopher G. Wise, Ph.D., analyzed survey responses of 797 chief administrators of rural hospitals about their service mix, financial strategies, and personnel during fiscal years 1982-1983 and 1987-1988, as well as secondary data from the American Hospital Association and other databases. The found that by FY 1987-1988, total profit margins had declined for both hospitals that had downsized and those which had not, but no statistical significance had emerged. In fact, hospitals that downsized actually had a significantly poorer current liquidity ratio by FY 1987-1988.

"Downsizing and Financial Performance in Rural Hospitals," *Health Care Management Review*, 21(2), pp. 16-25, 1996.

Cancer Surgery Becomes More Common among Elderly Patients

Although older persons are still less likely to undergo surgery for cancer than younger persons, the gap is narrowing, according to a new AHCPR-supported study. Researchers found that the age discrepancy diminished for certain cancer surgeries from 1973 through 1991. These increased cancer surgeries are due in part to the greater robustness of today's elderly, who are better able to tolerate the stresses of surgery.

During the past two decades the likelihood of surgical treatment for cancers of the uterus, colon, rectum, ovary, and breast increased more quickly among persons 65 years of age and older than younger ones. Even the oldest elderly now receive surgery for these common cancers. However, the age gap did not narrow for surgeries for cancer of the lung, stomach, and pancreas. Researchers at the Johns Hopkins University School of Hygiene and Public Health, who led the study, formulated their analysis using population-based National Cancer Institute data for nine U.S. regions.

"Temporal and Regional Variability in the Surgical Treatment of Cancer among Older People, March 1996," *Journal of the American Geriatrics Society*, pp. 559-564.

Amount of HIV in the Blood Signals Time until Aids Onset

The amount of time that it will take for persons infected with the human immunodeficiency virus (HIV) to develop Acquired Immunodeficiency Syndrome (AIDS) can be predicted by the amount of viral RNA in their blood. Researchers, led by Joseph Lau, M.D., of Tufts University School of Medicine, found that asymptomatic persons who have 100,000 HIV particles per milliliter of blood (viral load) are at risk of developing AIDS in less than three years, while persons with 500,000 particles per milliliter may develop AIDS in less than one year. In contrast, patients with a viral load of 50,000 have at least two years and may have up to eight years before developing AIDS.

CD lymphocyte cell count has been the standard indicator of HIV disease progression. However, since CD counts are usually normal in asymptomatic patients, knowing their HIV load will aid physicians to make better therapy decisions. If a patient's viral load continues to increase under current medication, the physician will be alerted to change medication. But for persons with advanced HIV disease, CD cell count may be better than viral load for predicting long-term outcomes.

"Predictive Value of Viral Load Measurements in Asymptomatic Untreated HIV-1 Infection: a Mathematical Model," *AIDS*, 10(3), pp.255-262, 1996.

Latinas and Black Women are Less Likely Than Other Women To Undergo Prenatal Tests to Detect Fetal Defects

Expectant Latinas and black women are much less likely to undergo amniocentesis and chorionic villus sampling to detect fetal defects than are white and Asian women, regardless of their occupation and education. In a study, conducted by researchers at the University of California, San Francisco, black women were one-third less likely; Latinas, were one-fourth less likely, and Asian women, were nearly twice as likely as white women to undergo prenatal testing.

"This suggests that attitudes toward prenatal testing, pregnancy termination, and/or raising a disabled child may differ across these racial-ethnic groups, transcending socioeconomic strata," comments Eugene Washington, M.D., M.Sc. of UCSF. "Alternatively, these women may not be receiving adequate, clearly understandable, and culturally sensitive information regarding the possible outcomes of testing or not testing." Dr. Washington and coinvestigators suggest that efforts be made to provide these women with such information.

"Racial-ethnic Differences in Prenatal Diagnostic Test Use and Outcomes: Preferences, Socioeconomics, or Patient Knowledge?," May 1996, *Obstetrics & Gynecology* 87, pp. 675-682.

Other Findings

Other articles in *Research Activities* include findings on:

- Deciding when to admit chest pain patients to the ICU
- Short-term survival of heart attack patients
- Admission to nursing homes: who gets in?
- Does insurance status affect hospital treatment?
- Impact of fewer minority physicians on care for minority patients
- Which physicians are leaving rural health care and why
- Hospital costs for stroke
- Effects of Medicaid on nursing home quality of care
- How to motivate urban black teenagers to use condoms
- Treatments for *Pneumocystis carinii* pneumonia
- Complications of AIDS-related medications
- Risk of retinal detachment following cataract surgery
- Surgery for spinal stenosis: a good idea?

- What determines women's satisfaction with prenatal care
- The high state costs of trauma care
- Insurance coverage of new medical technologies
- Free vaccines for providers: Will more children be immunized?

For additional information, contact AHCPR Public Affairs at (301) 594-1364: Karen Migdail, ext. 1375, or Salina Prasad, ext. 1317.

Return to AHCPR Press Release Index
Return to AHCPR Home Page

Health Care Use

Mohr, P.E.: Patterns of Health Care Use Among HIV-Infected Adults: Preliminary Results. *AIDS Cost and Services Utilization Survey (ACSUS) Report*, No. 3. AHCPR Pub. No. 94-0105. Rockville, MD: Agency for Health Care Policy and Research, 1994.

The AIDS Cost and Services Utilization Survey (ACSUS), a longitudinal study of persons with HIV-related disease, is the largest data collection effort targeting the population infected with HIV. In a combination of personal interviews and abstraction of medical and billing records spanning an 18-month period, information is collected on more than 1,900 HIV-infected adults and adolescents, including approximately 350 women, and on 140 HIV-infected children under 13 years of age. This report presents preliminary results from the first ACSUS interview. Controlling for self-reported disease stage, utilization is examined for hospital care, nursing home care, formal and informal home care, ambulatory medical visits, use of azidothymidine (AZT), psychological counseling, and dental services.

Traditionally disadvantaged groups differed from other groups in the types of health care services used. HIV-infected minorities, male injecting drug users and females, persons in the lowest income category, and the unemployed appear to use services on an emergency basis, being more likely than others to report a hospital stay or visit to an emergency room. In contrast, white persons and those in the highest income category were more likely than others to report a visit to a private physician's office, use of psychological counseling, and receipt of dental care services.

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Department of Health and Human Services Home Page

Clinical Studies

AIDS/HIV

Outcomes of Pharmaceutical Therapy of HIV Disease
Grant/Contract Number: HS07809
Project Period: 02/93-01/98
Principal Investigator: Richard D. Moore, M.D.
Institution: Johns Hopkins University
Baltimore, MD 21205

Purpose: To (1) develop a comprehensive longitudinal database of human immunodeficiency virus (HIV) infected individuals cared for in an urban setting, (2) examine the effectiveness of antiretroviral and antimicrobial therapies in preventing progression of HIV disease and its complications, (3) determine the association of surrogate laboratory markers with clinical outcomes, (4) delineate the frequency and consistency of prescription drug use, and (5) identify the sociodemographic and clinical patient characteristics associated with consistent use of and response to drug therapy.

Cost Effective Management of HIV Related Illness
Grant/Contract Number: HS06694
Project Period: 07/90-06/93
Principal Investigator: Anna N.A. Tosteson, Sc.D.
Institution: Dartmouth Medical School
Lebanon, NH 03756

Purpose: To (1) develop a model for HIV infected patients presenting with central nervous system disorders (CNS model), (2) integrate the CNS model with previously developed models for respiratory disorders, and (3) explore the feasibility of developing a natural clinical history model of HIV infection. The CNS model assessed the life expectancy, quality adjusted life expectancy, short term morbidity, cost, and cost effectiveness of all clinically reasonable management strategies.

A Health Status Measure to Evaluate Drug Therapy for PCP
Grant/Contract Number: HS07824
Project Period: 09/93-08/95
Principal Investigator: Albert W. Wu, M.D., M.P.H.
Institution: Johns Hopkins University
Baltimore, MD 21205

Purpose: To examine the reliability and validity of a brief health status measure for acquired immunodeficiency syndrome (AIDS) patients infected with Pneumocystis carinii pneumonia (PCP). The study analyzed data collected in a randomized AIDS clinical trial comparing three treatment regimens for acute PCP. The results help in planning future AIDS trials incorporating health status measures.

Cancer

Prostate Cancer: A Retrospective Survival Analysis
Grant/Contract Number: HS06770
Project Period: 04/91 - 07/94
Principal Investigator: Peter C. Albertsen, M.D., M.S.
Institution:University of Connecticut
Farmington, CT 06032-9984

Purpose: To calculate the disease-specific mortality rate for conservatively treated localized prostate cancer. Using a detailed retrospective analysis, the study compared this rate with the general population of men alive during the same time period. The implications of the findings for clinical practice and

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THE ASSISTANT SECRETARY OF DEFENSE

WASHINGTON, D. C. 20301-1200

HEALTH AFFAIRS

12 NOV 1997

Daniel C. Montoya
Executive Director
Presidential Advisory Council on HIV/AIDS
Office of National AIDS Policy
808 17th Street, NW, Suite 820
Washington, D. C. 20006

Dear Mr. Montoya:

This is in response to your memorandum for the Secretary of Defense dated July 22, 1997, in which you forwarded a May 6, 1997, letter expressing concern with current HIV/AIDS policies at the Department of Defense (DOD).

Fitness for duty and deployability are the essence of an effective military force. Current Department of Defense policies ensure that a fit and ready force are in place at all times. Since 1986, all prospective recruits, active duty members, and reservists have been periodically tested for the presence of HIV. Physical standards for appointment, enlistment, and induction into the armed forces, as addressed in attachment 1, Department of Defense Directive (DODD) 6130.3, clearly identify the many physical and mental conditions that preclude entry to active duty service; testing positive for HIV/AIDS is merely one of many. Chronic illness is exacerbated in settings of high physical and mental stress. To permit individuals with chronic conditions such as HIV/AIDS entry into military service could place both the individual and mission at risk.

Department of Defense Directive 6485.1, attachment 2, defines policy and procedures for identification, surveillance, and administration of civilian and military personnel infected with HIV. Extensive effort is made to allow HIV infected individuals to fully serve in the armed forces in situations that keep them from further harm, for as long as they are physically and mentally able. In addition to superb medical care, service members are offered psychological and spiritual counseling. There is some limitation to duty station assignments to keep HIV positive personnel close to the best medical care available. The military healthcare system does its utmost to ensure individual privacy by utilizing separate medical records for HIV positive individuals and HIV status is disclosed only on a "need to know" basis with respect to readiness issues.

The Department of Defense has been a pioneer in the research and treatment of HIV/AIDS. Our motivation is intrinsic to the loyalty and commitment we have to our service members. We continue to be national and international leaders in the development and implementation of safe and compassionate policies and procedures for HIV/AIDS.

Based on the information provided above, we are dismayed at being portrayed as lacking in the elimination of discriminatory policies regarding HIV/AIDS. In fact, the DOD has been a longstanding leader in opposing discrimination against those who suffer from HIV disease. The Department of Defense has a responsibility to the nation and world to maintain a fit and ready force and safeguard the service members entrusted to our care. Our policies are in place to accomplish both.

Sincerely,

Edward D. Martin

Edward D. Martin, M.D.
Acting Assistant Secretary of Defense

Attachments:
As stated

Department of Defense
DIRECTIVE

May 2, 1994
NUMBER 6130.3

ASD(HA)

SUBJECT: Physical Standards for Appointment, Enlistment, and Induction

References: (a) DoD Directive 6130.3 "Physical Standards for Enlistment, Appointment, and Induction," March 31, 1986 (hereby canceled)
(b) Section 115 of title 10, United States Code

A. REISSUANCE AND PURPOSE

1. This Directive reissues reference (a) to update policy, responsibilities, procedures, and standards for appointment, enlistment, and induction into the Armed Forces of the United States in accordance with reference (b).

2. The physical standards in this Directive (enclosure 1) are to ensure that individuals under consideration for appointment, enlistment, and induction into the Armed Forces of the United States are:

a. Free of contagious diseases that would be likely to endanger the health of other personnel.

b. Free of medical conditions or physical defects that would require excessive time lost from duty for necessary treatment or hospitalization or would likely result in separation from the Service for medical unfitness.

c. Medically capable of satisfactorily completing required training.

d. Medically adaptable to the military environment without the necessity of geographical area limitations.

e. Medically capable of performing duties without aggravation of existing physical defects or medical conditions.

B. APPLICABILITY AND SCOPE

This Directive:

1. Applies to the Office of the Secretary of Defense.

2. Applies to the Military Departments and, by agreement with the Secretary of Transportation, to the U.S. Coast Guard when it is not operating as a Military Service within the Navy (hereafter referred to collectively as the "Armed Forces"), and the Merchant Marine Academy.

3. Sets forth the medical conditions and physical defects that are causes for rejection for military service. Other standards may be prescribed for a mobilization for a national emergency. The physical standards (enclosure 1) apply to:

a. Applicants for appointment as commissioned or warrant officers in the Active and Reserve components.

b. Applicants for enlistment in the regular Armed Forces. For medical conditions or physical defects predating original enlistment, these standards obtain for enlistees' first 6 months of active duty.

c. Applicants for enlistment in the Reserve and federally recognized units or organizations of the National Guard. For medical conditions or physical defects predating original enlistment, these standards obtain during the enlistees' initial period of active duty for training until their return to Reserve component units.

d. Applicants for reenlistment in Regular and Reserve components and federally recognized units or organizations of the National Guard after a period of more than 6 months has elapsed since discharge.

e. Applicants for the Scholarship or Advanced Course Reserve Officer's Training Corps (ROTC), and all other Armed Forces' special officer personnel procurement programs.

f. Retention of cadets and midshipmen at the United States Armed Forces academies and students enrolled in ROTC scholarship programs.

g. Individuals on the Temporary Disability Retired List (TDRL) who have been found fit on reevaluation and wish to return to active duty. The prior disabling defect(s) and any other physical defects identified before placement on the TDRL that would not have prevented reenlistment are exempt from this Directive.

h. All individuals being inducted into the Armed Forces.

C. POLICY

1. It is DoD policy to:

a. Encourage to the maximum extent possible the use of common physical standards for the acquisition of personnel for the Armed Forces.

b. Eliminate inconsistencies and inequities based on race, sex, or ethnicity in the application of these standards by the Armed Forces.

2. The standards in enclosure 1 shall be used in the acquisition of personnel in the programs in subsection B.3., above.

D. RESPONSIBILITIES

1. The Under Secretary of Defense for Personnel and Readiness shall:

a. Ensure that the Assistant Secretary of Defense for Health Affairs (ASD(HA)) shall review, approve, and issue technical modifications to the standards in enclosure 1.

b. Implement these standards through the U.S. Military Entrance Processing Command (MEPCOM) and the DoD Medical Examination Review Board (DoDMERB).

c. Give direction to the ASD(HA) on the personnel aspects of these standards.

2. The Secretaries of the Military Departments shall:

a. Revise their Armed Forces policies to conform with the standards in this Directive.

b. Recommend to the Office of the Assistant Secretary of Defense Health Affairs (OASD(HA)) suggested changes in the standards after departmental coordination has been accomplished.

c. Review all the standards on a quadrennial basis and recommend changes to the OASD(HA). This review shall be initiated by the DoDMERB and coordinated by the OASD(HA).

d. Have authority to grant a waiver of the standards in individual cases for appropriate reasons.

e. Have authority to change Service-specific visual standards (particularly for officer-accession programs) and establish other standards for special programs. Notification of any proposed changes in standards shall be provided to the ASD(HA) 60 days before their implementation.

f. Have the authority to issue Service-specific exceptions to these standards, having first submitted these, with justification, for review and approval by the ASD(HA).

E. PROCEDURES

The physical standards (enclosure 1) shall be used to determine the physical qualifications of all individuals being appointed, enlisted, or inducted into the Armed Forces.

F. EFFECTIVE DATE AND IMPLEMENTATION

This Directive is effective immediately. Forward one copy of implementing documents to the Under Secretary of Defense for Personnel and Readiness within 120 days.

John M. Deutch
Deputy Secretary of Defense

Enclosure - 1
1. Physical Standards for Appointment, Enlistment, and Induction

PHYSICAL STANDARDS FOR APPOINTMENT, ENLISTMENT, AND INDUCTION

TABLE OF CONTENTS

PHYSICAL STANDARDS FOR APPOINTMENT, ENLISTMENT, AND INDUCTION

A. ABDOMINAL ORGANS AND GASTROINTESTINAL SYSTEM

The causes for rejection for appointment, enlistment, and induction are:

1. Esophagus. Organic disease or authenticated history of, such as ulceration, varices, achalasia, or other dismotility disorders; chronic or recurrent esophagitis if confirmed by appropriate X-ray or endoscopic examinations.

2. Stomach and Duodenum

a. Gastritis, chronic hypertrophic, severe.

b. Ulcer of the stomach or duodenum, if diagnosis is confirmed by X-ray examinations, endoscopy, or authenticated history thereof.

c. Authenticated history of surgical operation(s) for gastric or duodenal ulcer; i.e., partial or total gastric resection, gastrojejunostomy, pyloroplasty, and truncal or selective vagotomy (or history of such operative procedures for any other cause or diagnosis).

d. Duodenal diverticula with symptoms or sequelae (hemorrhage, perforation, etc.).

e. Congenital abnormalities of the stomach or duodenum causing symptoms or requiring surgical treatment, except a history of surgical correction of hypertrophic pyloric stenosis of infancy is not disqualifying if currently asymptomatic.

3. Small and Large Intestine

a. Intestinal obstruction or authenticated history of more than one episode if either occurred during the preceding 5 years or if resulting condition remains, producing significant symptoms or requiring treatment.

b. Symptomatic Meckel's diverticulum.

c. Megacolon of more than minimal degree.

d. Inflammatory lesions: diverticulitis, regional enteritis, ulcerative colitis, proctitis.

e. Intestinal resection; however, minimal intestinal resection in infancy or childhood (e.g., for intussusception) is acceptable if the individual has been asymptomatic since the resection and if the appropriate consultant finds no residual impairment.

f. Malabsorption syndromes.

4. Gastrointestinal Bleeding. History of, unless the cause has been corrected and is not otherwise disqualifying.

5. Hepato-Pancreatic-Biliary Tract

a. Hepatitis within the preceding 6 months or persistence of symptoms after 6 months, with objective evidence of impairment of liver function, and chronic hepatitis, including hepatitis B carriers.

b. Hepatic Cysts. Congenital cystic disease, parasitic, protozoal, or other cysts.

c. Cirrhosis, regardless of the absence of manifestations such as jaundice, ascites, or known esophageal varices; abnormal liver function, with or without history of chronic alcoholism.

d. Cholecystectomy, sequelae of, such as postoperative stricture of the common bile duct, reforming of stones in hepatic or common bile ducts, incisional hernia, or postcholecystectomy syndrome when symptoms are of such a degree as to interfere with normal performance of duty.

e. Cholecystitis, acute or chronic, with or without cholelithiasis.

f. Bile duct abnormalities or strictures.

g. Pancreas, acute or chronic disease of, if proven by laboratory tests or medical records; and congenital anomalies such as annular pancreas, cystic disease, etc.

6. Anorectal

a. Fistula in ano.

b. Incontinence.

c. Anorectal stricture.

d. Excessive mucous production with soiling.

e. Hemorrhoids, internal or external, when large, symptomatic, or history of bleeding.

f. Rectal prolapse.

g. Symptomatic rectocele.

h. Symptomatic anal fissure.

i. Chronic diarrhea, regardless of cause.

7. Spleen

a. Splenomegaly until the cause is corrected and is not otherwise disqualifying.

b. Splenectomy, except when accomplished for the following:

(1) Trauma.

(2) Causes unrelated to diseases of the spleen.

(3) Hereditary spherocytosis.

(4) Disease involving the spleen when followed by correction of the condition for at least 2 years and is not otherwise disqualifying.

8. Tumors (See section LL., below.)

9. Abdominal Wall

a. Scars

(1) Scars, abdominal, regardless of cause, the hernial bulging of which interferes with movement.

(2) Scar pain associated with disturbance of function of abdominal wall or contained viscera.

(3) Sinuses of the abdominal wall, to include persistent urachus and persistent omphalomesenteric duct.

b. Hernia

(1) Hernia other than small asymptomatic umbilical or asymptomatic hiatal.

(2) History of operation for hernia within the preceding 60 days.

10. Other. Congenital or acquired abnormalities, such as gastrointestinal bypass or stomach stapling for control of obesity; and defects that prevent satisfactory performance of military duty or require frequent and prolonged treatment.

B. BLOOD AND BLOOD-FORMING TISSUE DISEASES

The causes for rejection for appointment, enlistment, and induction are:

1. Anemia. Any hereditary or acquired anemia that cannot be permanently corrected with therapy before appointment or induction.

2. Hemorrhagic Disorders. Any congenital or acquired state resulting in a tendency to bleed due to a platelet, coagulation, or vascular abnormality.

3. Leukopenia. Chronic or recurrent, associated with increased susceptibility to infection.

4. Myeloproliferative Disease. Myeloproliferative or myelodysplastic disease, or history thereof.

5. Thromboembolic Disease. Thromboembolism at any time.

6. Immunodeficiency Diseases. Any congenital or acquired immunodeficiency state regardless of etiology.

7. Miscellaneous Conditions. Such as porphyria, hemachromatosis, amyloidosis, and post-splenectomy status (except when secondary to causes stated in subsection A.7. of this enclosure, above.)

C. DENTAL

The causes for rejection for appointment, enlistment, and induction are:

1. Diseases of the jaw or associated tissues that are not easily remediable and will incapacitate the individual or otherwise prevent the satisfactory performance of duty. This includes temporomandibular disorders and/or myofacial pain dysfunction that is not easily corrected.

2. Severe malocclusion that interferes with normal mastication or requires early and protracted treatment; or relationship between mandible and maxilla that prevents satisfactory future prosthodontic replacement.

3. Insufficient natural healthy teeth or lack of a serviceable prosthesis, preventing adequate mastication and incision of a normal diet. This includes complex (multiple fixture) dental implant systems that have associated complications that severely limit assignments and adversely affect performance of world-wide duty. Dental implants that are no longer functional must not interfere with continuation of wear of the implant prosthesis or prevent removal and replacement with a conventional prosthesis.

4. Orthodontic Appliances for Continued Treatment (attached or removable). Retainer appliances are permissible, provided all active orthodontic treatment has been satisfactorily completed.

D. EARS

The causes for rejection for appointment, enlistment, and induction are:

1. Auditory Canal

a. Atresia or severe stenosis of the external auditory canal.

b. Tumors of the external auditory canal except mild exostoses.

c. Severe external otitis, acute or chronic.

2. Auricle. Microtia, severe; or severe traumatic deformity, unilateral or bilateral.

3. Mastoids

a. Mastoiditis, acute or chronic.

b. Residual of mastoid operation with marked external deformity that prevents or interferes with the wearing of a protective mask or helmet.

c. Mastoid fistula.

4. Meniere's Syndrome.

5. Middle Ear

a. Acute or chronic otitis media of any type.

b. Presence of attic perforation in which presence of cholesteatoma is suspected.

c. History of surgery involving the middle ear, excluding myringotomy.

d. Cholesteatoma or history thereof.

6. Tympanic Membrane

a. Any perforation of the tympanic membrane.

b. Surgery to repair perforated tympanic membrane within 120 days.

c. Thickening or scarring of the tympanic membrane associated with hearing level by audiometric test of 30 dB or more average for the speech frequencies (500, 1000, and 2000 cycles per second) in either ear regardless of the hearing level in the other ear.

7. Other diseases and defects of the ear that obviously prevent satisfactory performance of duty or that require frequent and prolonged treatment.

E. HEARING (See also section D. of this enclosure, above.)

The cause for rejection for appointment, enlistment, and induction is a hearing threshold level greater than that described in paragraph E.1.c., below.

1. Audiometric Hearing Levels

a. Audiometers, calibrated to the International Standards Organization (ISO 1964) or the American National Standards Institute (ANSI 1969), shall be used to test the hearing of all applicants for appointment, enlistment, or induction.

b. All audiometric tracings or audiometric readings recorded on reports of medical examination or other medical records shall be clearly identified.

c. Acceptable Audiometric Hearing Levels are:

(1) Pure tone at 500, 1000, and 2000 cycles per second of not more than 30dB on the average (either ear), with no individual level greater than 35dB at these frequencies.

(2) Pure tone level not more than 45dB at 3000 cycles per second each ear, and 55dB at 4000 cycles per second each ear.

F. ENDOCRINE AND METABOLIC DISORDERS

The causes for rejection for appointment, enlistment, and induction are:

1. Adrenal dysfunction of any degree.

2. Cretinism.

3. Diabetes Mellitus. Any type, including a history of juvenile onset (insulin-dependent, type I).

4. Gigantism or Acromegaly.

5. Glycosuria. Persistent, when associated with impaired glucose tolerance or renal tubular defects that cause aminoaciduria, phosphaturia, and renal tubular acidosis.

6. Gout.

7. Hyperinsulinism.

8. Hyperparathyroidism and Hypoparathyroidism.

9. Hypopituitarism.

10. Myxedema. Spontaneous or postoperative (with clinical manifestations).

11. Nutritional deficiency diseases (including sprue, beriberi, pellagra, and scurvy).

12. Thyroid Disorders.

a. Goiter. Simple goiter with definite pressure symptoms, or so large as to interfere with the wearing of a military uniform or military equipment.

b. Hyperthyroidism or thyrotoxicosis.

c. Hypothyroidism, symptomatic or uncontrolled by medication.

d. Thyroiditis.

13. Other endocrine or metabolic disorders that obviously prevent satisfactory performance of duty, or require frequent or prolonged treatment.

G. UPPER EXTREMITIES (See also section I., below.)

The causes for rejection for appointment, enlistment, and induction are:

1. Limitation of Motion. An individual shall be considered unacceptable if the joint ranges of motion are less than the measurements listed below. (Methods of measurement appear in U.S. Army Technical Manual (TM) 8-6 and U.S. Air Force Pamphlet (AFP) 160.14.)

a. Shoulder

(1) Forward elevation to 90°.

(2) Abduction to 90°.

b. Elbow

(1) Flexion to 100°.

(2) Extension to 15°.

c. Wrist. A total range of 60° (extension plus flexion). Radial and ulnar deviation combined arc 30°.

d. Hand

(1) Pronation to 45°.

(2) Supination to 45°.

e. Fingers. Inability to clench fist, pick up a pin or needle, and grasp an object.

f. Thumb. Inability to touch tips of at least 3 fingers.

2. Hand and Fingers

a. Absence of the distal phalanx of either thumb.

b. Absence or loss of distal and middle phalanx of an index, middle, or ring finger of either hand irrespective of the absence or loss of little finger.

c. Absence of more than the distal phalanx of any two of the following fingers: index, middle finger, or ring finger of either hand.

d. Absence of hand or any portion thereof except for fingers as noted above.

e. Hyperdactylia.

f. Scars and deformities of the fingers or hand that impair circulation, are symptomatic, or which impair normal function to such a degree as to interfere with the satisfactory performance of military duty.

g. Intrinsic paralysis or weakness (either median or ulnar nerves) sufficient to produce physical findings in the hand (e.g., muscle atrophy or weakness).

3. Wrist, Forearm, Elbow, Arm, and Shoulder. Recovery from disease or injury of wrist, forearm, elbow, arm, or shoulder with residual weakness or symptoms such as to prevent satisfactory performance of duty. Grip strength of less than 75 percent of predicted normal when injured hand is compared with the normal hand (nondominant is 80 percent of dominant grip).

H. LOWER EXTREMITIES (See also section I., below.)

The causes for rejection for appointment, enlistment, and induction are:

1. Limitation of Motion. An individual shall be considered unacceptable if the joint ranges of motion are less that the measurements listed below. (Methods of measurement appear in TM 8-640 and AFP 160-14.)

a. Hip

(1) Flexion to 90°.

(2) No demonstrable flexion contracture.

(3) Extension to 10° (beyond 0°).

(4) Abduction to 45°.

(5) Rotation - 60° (internal and external combined).

b. Knee

(1) Full extension.

(2) Flexion to 90°.

c. Ankle

(1) Dorsiflexion to 10°.

(2) Plantar flexion to 30°.

(3) Eversion and inversion (total to 5°).

d. Toes

Stiffness that interferes with walking, marching, running, or jumping.

2. Foot and Ankle

a. Absence of one or more small toes if function of the foot is poor, or running or jumping is prevented; absence of a foot or any portion thereof except for toes as noted herein.

b. Absence of great toe(s); loss of dorsal flexion thereof if function of the foot is impaired.

c. Claw toes preventing the wearing of military footwear.

d. Clubfoot if any residual varus or equinus of the hind foot, degenerative changes in the mid or hind foot or significant stiffness or deformity prevents foot function or wearing military footwear.

e. Pes planus, pronounced cases, with decided eversion of the foot and marked bulging of the inner border, due to rotation of the talus, regardless of the presence or absence of symptoms.

f. Pes planus, tarsal coalition.

g. Hallux valgus, if severe, or of any degree if associated with marked exostosis or bunion that would prevent wearing of military footwear.

h. Hammer toe, hallux limitus, or hallux rigidus that interferes with the wearing of military footwear.

i. Effects of disease, injury, or deformity including hyperdactylia that prevent running, are accompanied by disabling pain, or prohibit the wearing of military footwear.

j. Ingrowing toe nails, if severe, and not remediable.

k. Obliteration of the transverse arch associated with permanent flexion of the small toes.

l. Overriding of any of the toes if symptomatic or sufficient to interfere with the wearing of military footwear.

m. Pes cavus, symptomatic or with contracted plantar fascia, dorsiflexed toes, tenderness under the metatarsal heads, or callosities under the weight bearing areas.

n. Planter fasciitis, that is refractory to medical treatment or will impair function of the foot.

o. Neuroma. Confirmed and refractory to medical treatment or will impair function of the foot.

3. Leg, Knee, Thigh, and Hip

a. Loose or foreign bodies within the knee joint.

b. Physical findings of an unstable or internally deranged joint. History of anterior or posterior cruciate ligament injury, even if repaired, is disqualifying.

c. History of surgical correction of knee ligaments.

d. Authenticated history of congenital dislocation of the hip, osteochondritis of the hip (Legg-Perthes disease), or slipped femoral epiphysis of the hip. These conditions are not disqualifying if there is no X-ray evidence of residual deformity or degenerative changes, or with any clinically significant limitation of motion.

e. Authenticated history of hip dislocation within 2 years before examination or degenerative changes on X-ray from old hip dislocation.

f. Osteochondritis of the tibial tuberosity (Osgood-Schlatter disease) if symptomatic or with obvious prominence of the part, and X-ray evidence of separated bone fragment.

4. General

a. Deformities of one or both lower extremities that have interfered with function to such a degree as to prevent the individual from following a physically active vocation in civilian life or that would interfere with the satisfactory completion of prescribed training and performance of military duty.

b. Diseases or deformities of the hip, knee, or ankle joint that interfere with walking, running, or weight bearing.

c. Pain in the lower back or leg that is intractable and disabling to the degree of interfering with walking, running, and weight bearing.

d. Shortening of a lower extremity resulting in a noticeable limp or scoliosis.

I. MISCELLANEOUS CONDITIONS OF THE EXTREMITIES (See also sections G. and H. of this enclosure above.)

The causes for rejection for appointment, enlistment, and induction are:

1. Arthritis

a. Active, subacute, or chronic arthritis.

b. Chronic osteoarthritis or traumatic arthritis of isolated joints of more than a minimal degree that has interfered with the following of a physically active vocation in civilian life or that prevents the satisfactory performance of military duty.

2. Chronic retropatellar knee pain syndrome with or without confirmatory arthoscopic evaluation.

3. Disease of any bone or joint, healed, with such resulting deformity or rigidity that function is so impaired it will interfere with military service.

4. Dislocation, old unreduced; substantiated history of recurrent dislocations of major joints; instability of a major joint.

5. Fractures

a. Malunited fractures.

b. Ununited fractures, except for ulnar styloid process.

c. Any old or recent fracture in which a plate, pin, metal rod, wire, or screws used for fixation were left in place; a pin, wire, or screw not subject to easy trauma is not disqualifying.

6. Injury of a bone or joint of more than a minor nature, yet without fracture or dislocation, that occurred within the preceding 6 weeks.

7. Joint replacement.

8. Muscular paralysis, contracture, or atrophy, if progressive or of sufficient degree to interfere with military service.

9. Myotonia Congenita.

10. Osteochondritis Dessicans.

11. Osteochondromatosis or multiple cartilaginous exostoses.

12. Osteomyelitis. Active or recurrent, any bone or substantiated history of osteomyelitis of any of the long bones.

13. Osteoporosis.

14. Scars. Extensive, deep, or adherent to the skin and soft tissues or neuromas of an extremity that are painful, that interfere with muscular movements, that prevent the wearing of military clothing or equipment, or that show a tendency to break down.

15. Implants. Silastic or other devices implanted to correct orthopedic abnormalities.

J. EYES

The causes for rejection for appointment, enlistment, and induction are:

1. Lids

a. Blepharitis, chronic, of more than mild degree. Cases of acute blepharitis will be rejected until cured.

b. Blepharospasm.

c. Dacryocystitis, acute or chronic.

d. Destruction of the lids, complete or extensive, sufficient to impair protection of the eye from exposure.

e. Adhesions of the eyelids to each other or to the eyeball that interfere with vision.

f. Growth or tumor of the eyelid other than small early basal cell tumors of the eyelid, which can be cured by treatment, and small nonprogressive asymptomatic benign lesions. (See also section LL. of this enclosure, below.)

g. Marked inversion or eversion of the eyelids sufficient to cause troublesome watering of eyes (entropion or ectropion).

h. Lagophthalmos.

i. Ptosis interfering with vision.

j. Trichiasis, severe.

2. Conjunctive

a. Conjunctivitis, chronic, including trachoma; allergic conjunctivitis; acute conjunctivitis until cured.

b. Pterygium.

(1) Recurring after two operative procedures.

(2) Encroaching on the cornea in excess of 3 millimeters, interfering with vision, or is progressive (as evidenced by marked vascularity on a thickened elevated head).

c. Xerophthalmia.

3. Cornea

a. Dystrophy, corneal, of any type, including keratoconus of any degree.

b. History of keratorefractive surgery accomplished to modify the refractive power of the cornea, or of lamellar and/or penetrating keratoplasty. Laser surgery to reconfigure the cornea is also disqualifying.

c. Keratitis, acute or chronic.

d. Ulcer, corneal; history of recurrent ulcers or corneal abrasions (including herpetic ulcers).

e. Vascularization or opacification of the cornea from any cause that is progressive or reduces vision below the standards prescribed in section K. of this enclosure, below.

4. Uveal Tract. Inflammation of the uveal tract except healed traumatic choroiditis.

5. Retina

a. Angiomatoses, phakomatoses, retinal cysts, and other congenito-hereditary conditions that impair visual functions.

b. Chorioretinitis, unless single episode that has healed and does not interfere with vision.

c. Degenerations of the macula to include macular cysts, holes, and other degenerations (hereditary or acquired degenerative changes and other conditions affecting the macula, including all types of primary and secondary pigmentary degenerations).

d. Detachment of the retina, history of surgery for same, or peripheral retinal injury or degeneration that may cause retinal detachment.

e. Inflammation of the retina (histoplasmosis, toxoplasmosis, or vascular conditions of the retina to include Coats' disease, diabetic retinopathy, Eales' disease, and retinitis proliferans), unless a single episode that has healed and does not interfere with vision.

6. Optic Nerve

a. Congenito-hereditary conditions of the optic nerve or any other central nervous system pathology affecting the efficient function of the optic nerve.

b. Optic neuritis, neuroretinitis, or secondary optic atrophy resulting therefrom or documented history of attacks of retrobulbar neuritis.

c. Optic atrophy (primary or secondary).

d. Papilledema.

7. Lens

a. Aphakia (unilateral or bilateral), pseudophakia, or lens implant.

b. Dislocation, partial or complete, of a lens.

c. Opacities of the lens that interfere with vision or that are considered to be progressive.

8. Ocular Mobility and Motility

a. Diplopia, documented, constant or intermittent from any cause or of any degree.

b. Nystagmus, with both eyes fixing, congenital or acquired.

c. Strabismus of 40 prism diopters or more, uncorrectable by lenses to less than 40 diopters.

d. Strabismus of any degree accompanied by documented diplopia.

e. Strabismus, surgery for the correction of, within the preceding 6 months.

f. For entrance into Service academies and ROTC programs, additional requirements relating to esotropia and hypertropia may be set by the individual Military Services.

9. Miscellaneous Defects And Diseases

a. Abnormal conditions of the eye or visual fields due to diseases of the central nervous system. Meridian-specific visual field minimums are:

(1)	Temporal	85°
(2)	Superior-Temporal	55°
(3)	Superior	45°
(4)	Superior Nasal	55°
(5)	Nasal	60°
(6)	Inferior Nasal	50°
(7)	Inferior	65°
(8)	Inferior Temporal	85°

b. Absence of an eye.

c. Asthenopia, severe.

d. Exophthalmos, unilateral or bilateral, non-familial.

e. Glaucoma, primary, or secondary, or pre-glaucoma as evidenced by intraocular pressure above 21 mmHg, or the secondary changes in the optic disc or visual field loss associated with glaucoma.

f. Hemianopsia of any type.

g. Loss of normal pupillary reflex reactions to light or accommodation to distance or Adie's syndrome.

h. Loss of visual fields due to organic disease.

i. Night blindness.

j. Residuals of old contusions, lacerations, penetrations, etc., impairing visual function required for satisfactory performance of military duty.

k. Retained intraocular foreign body.

l. Tumors. (See subparagraph J.1.f., above, and section LL., below.)

m. Any organic disease of the eye or adnexa not specified above, that threatens vision or visual function.

K. VISION

The causes of medical rejection for appointment, enlistment, and induction are listed below. (For entrance into Service academies and ROTC programs, additional requirements on vision may be set by the individual Military Services. Special administrative criteria for assignment to certain specialties will be published by the Military Services.)

1. Distant Visual Acuity. Distant visual acuity of any degree that does not correct with spectacle lenses to at least one of the following:

a. 20/40 in one eye and 20/70 in the other eye.

b. 20/30 in one eye and 20/100 in the other eye.

c. 20/20 in one eye and 20/400 in the other eye.

2. Near Visual Acuity. Near visual acuity of any degree that does not correct to 20/40 in the better eye.

3. Refractive Error. Any refractive error in spherical equivalent of worse than -8.00 or +8.00 diopters; or if ordinary spectacles cause discomfort by reason of ghost images, prismatic displacement, etc.; if an ophthalmological consultation reveals a condition that is disqualifying; or if refractive error is corrected by orthokeratology or keratorefractive surgery.

4. Contact Lenses. Complicated cases requiring contact lenses for adequate correction of vision, such as keratoconus, corneal scars, and irregular astigmatism.

5. Color Vision. Although there is no standard, color vision will be tested, since adequate color vision is a prerequisite for entry into many military specialties. For entrance into Service academies and ROTC programs, color vision requirements may be set by the individual Services.

L. GENITALIA (See also section LL., below.)

The causes for rejection for appointment, enlistment, and induction are:

1. Abnormal uterine bleeding. Including menorrhagia, metrorrhagia or polymenorrhea.

2. Amenorrhea. Primary or secondary, if unexplained or otherwise disqualifying.

3. Dysmenorrhea. Incapacitating to a degree recurrently necessitating absences of more than a few hours from routine activities.

4. Endometriosis, or confirmed history thereof.

5. Hermaphroditism.

6. Hydrocele or Left Varicocele. If painful, or any right varicocele unless urological evaluation reveals no disease.

7. Menopausal Syndrome. Physiologic or artificial if manifested by more than mild constitutional or mental symptoms, or artificial menopause if less than 13 months have elapsed since cessation of menses. In all cases of artificial menopause, the clinical diagnosis will be reported; if accomplished by surgery, the pathologic report shall be obtained and recorded.

8. Ovarian cysts. Persistent, clinically significant.

9. Pelvic inflammatory disease (PID). Acute or chronic.

10. Pregnancy.

11. Testicle(s). (See also section LL., below.)

a. Absence of both testicles, or unexplained absence of a testicle.

b. Undiagnosed enlargement or mass of testicle or epididymis.

c. Undescended testicle(s).

12. Urethritis. Acute or chronic. (See also section MM., below.)

13. Uterus

a. Congenital absence of.

b. Generalized enlargement of the uterus due to any cause.

c. Pap smears graded Class 3 or 4, or any smear in which the descriptive terms condyloma accuminatum, human papilloma virus, dysplasia, carcinoma-in-situ, or invasive cancer are used.

14. Vagina

a. Congenital abnormalities that interfere with physical activities.

b. Condyloma accuminatum.

15. Vulva

a. Condyloma accuminatum.

b. Dystrophic conditions.

c. Vulvitis, acute or chronic, including herpes genitalis.

16. Major Abnormalities and Defects of the Genitalia. Such as a change of sex, a history thereof, or dysfunctional residuals from surgical correction of these conditions.

M. URINARY SYSTEM (See sections F., above, and LL., below.)

The causes for rejection for appointment, enlistment, and induction are:

1. Cystitis, Chronic. Individuals with acute cystitis are unacceptable until the condition is cured.

2. Enuresis. Determined to be a symptom of an organic defect not amenable to treatment. (See also subsection DD.3., below.)

3. Epispadias or Hypospadias. When accompanied by evidence of infection of the urinary tract, or if clothing is soiled when voiding.

4. Hematuria, cylinduria, pyuria, or other findings indicative of renal tract disease.

5. Incontinence of urine.

6. Kidney

a. Absence of one kidney, regardless of cause.

b. Acute or chronic infections of the kidney.

c. Cystic or polycystic kidney, confirmed history of.

d. Horseshoe kidney.

e. Hydronephrosis or pyonephrosis.

f. Nephritis, acute or chronic.

g. Pyelitis, pyelonephritis.

7. Orchitis, chronic, or chronic epididymitis.

8. Penis, amputation of, if the resulting stump is insufficient to permit micturition in a normal manner.

9. Peyronie's disease.

10. Prostate gland, hypertrophy of, with urinary retention; chronic prostatitis.

11. Proteinuria under normal activity (at least 48 hours after strenuous exercise) greater than 200 mgm/24 hours or a protein to creatinine ratio greater than 0.2 in a random urine sample, unless nephrologic consultation determines the condition to be benign orthostatic proteinuria.

12. Renal Calculus

a. Substantiated history of recurrent renal calculus or bilateral renal calculus at any time.

b. Verified history of renal calculus with evidence of stone formation within the preceding 12 months, current symptoms, or positive x-ray for calculus, or nephrocalcinosis.

13. Skenitis.

14. Urethra, stricture of.

15. Urinary fistula.

16. Other diseases and defects of the urinary system that obviously prevent satisfactory performance of duty or require frequent and prolonged treatment.

N. HEAD

The causes for rejection for appointment, enlistment, and induction are:

1. Abnormalities that are apparently temporary in character resulting from recent injuries until a period of 3 months has elapsed. These include severe contusions and other wounds of the scalp and cerebral concussion. (See section Z., below.)

2. Chronic Arthritis. Complete or partial ankylosis, or recurrent dislocation of the temporomandibular joint.

3. Deformities of the Skull. In the nature of depressions, exostoses, etc., of a degree that would prevent the individual from wearing a protective mask or military headgear.

4. Deformities of the Skull. Of any degree associated with evidence of disease of the brain, spinal cord, or peripheral nerves.

5. Depressed fractures that required surgical elevation or were associated with a laceration of the dura mater or focal necrosis of the brain. (See section Z., below.)

6. Loss or congenital absence of the bony substance of the skull not successfully corrected by reconstructive materials.

7. All cases involving absence of the bony substance of the skull that have been corrected but in which the defect is in excess of one square inch ($6.45cm^2$) or the size of a 25-cent piece.

O. NECK

The causes for rejection for appointment, enlistment, and induction are:

1. Cervical Ribs. If symptomatic, or so obvious that they are found on routine physical examination. (Detection based primarily on x-rays is not considered to meet this criterion.)

2. Congenital Cysts. Of branchial cleft origin or those developing from the remnants of the thyroglossal duct, with or without fistulous tracts.

3. Fistula. Chronic draining, of any type.

4. Nonspastic Contraction. Of the muscles of the neck or cicatricial contracture of the neck to the extent that it interferes with the wearing of a uniform or military equipment or is so disfiguring as to make the individual objectionable in common social relationships.

5. Spastic Contraction. Of the muscles of the neck, persistent, and chronic.

6. Tumor of thyroid or other structures of the neck. (See section LL., below.)

P. HEART

The causes for rejection for appointment, enlistment, and induction are:

1. All Valvular Heart Diseases. Including those improved by surgery, except mitral valve prolapse and bicuspid aortic valve. These latter two conditions are not reasons for rejection unless there is associated tachyarrhythmia, mitral regurgitation, aortic stenosis, insufficiency, or cardiomegaly.

2. Coronary heart disease.

3. History of Symptomatic Arrhythmia (or electrocardiographic evidence of arrhythmia)

a. Supraventricular tachycardia, atrial flutter, and atrial fibrillation unless there has been no recurrence during the preceding 2 years off all medications. Ventricular tachycardia or fibrillation. Premature atrial or ventricular contractions are disqualifying when sufficiently symptomatic to require treatment or result in physical or psychological impairment. Multifocal premature ventricular contractions are disqualifying irrespective of symptoms or treatment. However, healthy highly trained individuals can have multifocal premature ventricular contractions or nonsustained ventricular tachycardia with a normal prognosis. Cases may be considered on an individual basis by each Service waiver authority. Ventricular arrythmias are disqualifying when associated with physiologic or actuarial significance.

b. Left bundle branch block, Mobitz type II second degree AV block, third degree AV block, accelerated AV conduction (Wolff-Parkinson-White syndrome) and Lown-Ganong-Levine syndrome associated with an arrhythmia. Conduction disturbances such as first degree AV block, left anterior hemiblock, right bundle branch block or Mobitz type I second degree AV block are not disqualifying when asymptomatic and are not associated with underlying cardiovascular disease.

4. Hypertrophy or Dilatation of the Heart. As evidenced by chest x-ray, electrocardiogram, or echocardiogram. Cardiomyopathy, myocarditis, or history of congestive heart failure from any cause even though currently compensated. Care must be taken to avoid rejection of highly conditioned individuals with sinus bradycardia, increased cardiac volume, and apparent abnormal cardiac enlargement, as indicated by EKG and x-ray.

5. Pericarditis. Except in individuals who have been free of symptoms for 2 years and manifest no evidence of cardiac restriction or persistent pericardial effusion.

6. Persistent tachycardia (resting pulse rate of 100 or greater), regardless of cause.

7. Congenital Anomalies. Of heart and great vessels with physiologic or actuarial significance, which have not been totally corrected.

Q. VASCULAR SYSTEM

The causes for rejection for appointment, enlistment, and induction are:

1. Abnormalities of the arteries and blood vessels, aneurysms, atherosclerosis, arteritis.

2. Hypertensive Vascular Disease. Evidenced by three consecutive averaged diastolic blood pressure measurements greater than 90 mmHg or three consecutive averaged systolic pressures greater than 140 mmHg. High blood pressure requiring medication or a history of treatment including dietary restriction.

3. Pulmonary or systemic embolization, (history of).

4. Vasomotor Disturbance. Including orthostatic hypotension and Raynaud's phenomenon.

5. Vein Diseases. Recurrent thrombophlebitis, thrombophlebitis during the preceding year, or any evidence of venous incompetence, such as large or symptomatic varicose veins, edema, or skin ulceration.

R. HEIGHT

The causes for rejection for appointment, enlistment, and induction will be established by the Military Services.

S. WEIGHT

The causes for rejection for appointment, enlistment, and induction will be established by the Military Services. Body composition measurements may be used as the final determinant in evaluating an applicant's acceptability.

T. BODY BUILD

The causes for rejection for appointment, enlistment, and induction are:

1. Congenital malformation of bones and joints. (See sections G., H., and I., above.)

2. Deficient muscular development that would interfere with the completion of required training.

3. Evidence of congenital asthenia or body build that would interfere with the completion of required training.

U. LUNGS, CHEST WALL, PLEURA, AND MEDIASTINUM

The causes for rejection for appointment, enlistment, and induction are:

1. Abnormal elevation of the diaphragm, either side.

2. Abscess of the lung.

3. Acute infectious processes of the lung, chest wall, pleura, or mediastinum, until cured.

4. Asthma, including reactive airway disease, exercise induced bronchospasm or asthmatic bronchitis, reliably diagnosed at any age. Note: Reliable diagnostic criteria should consist of any of the following elements: (a) substantiated history of cough, wheeze, and/or dyspnea that persists or recurs over a prolonged period of time (generally more than 6 months), or if the diagnosis of asthma is in doubt, (b) a test for reversible airflow obstruction (greater than a 15% increase in FEV1 following administration of an inhaled bronchodilator), or airway hyperreactivity (exaggerated decrease in airflow induced by a standard bronchoprovocation challenge such as methacholine inhalation or a demonstration of exercise-induced bronchospasms) must be performed. Bronchoprovocation or exercise testing should be performed by a board certified pulmonologist or allergist.

5. Bronchitis, chronic, with pulmonary function impairment that would interfere with duty performance or restrict activities.

6. Bronchiectasis.

7. Bronchopleural fistula.

8. Bullous or generalized pulmonary emphysema.

9. Chronic fibrous pleuritis of sufficient extent to interfere with pulmonary function, or which produces dyspnea on exertion.

10. Chronic mycotic diseases of the lung including coccidioidomycosis, residual cavitation or more than a few small-sized inactive and stable residual nodules demonstrated to be due to mycotic disease.

11. Congenital malformation or acquired deformities of the chest wall that reduce the chest capacity or diminish respiratory or cardiac functions to a degree that interferes with vigorous physical exertion.

12. Empyema, residual intrapleural collection or unhealed sinuses of chest wall following operation or other treatment for empyema.

13. Extensive pulmonary fibrosis from any cause, producing dyspnea on exertion or significant reduction in pulmonary function tests.

14. Foreign body in trachea or bronchus.

15. Foreign body of the chest wall causing symptoms.

16. Foreign body of the lung or mediastinum causing symptoms or active inflammatory reaction.

17. Lobectomy, history of, with residual pulmonary disease. Removal of more than one lobe is cause for rejection regardless of the absence of residuals.

18. Multiple cystic disease of the lung; solitary cyst, large and incapacitating.

19. New growth of the breast, mastectomy, acute mastitis, chronic cystic mastitis of more than mild degree or if symptomatic.

20. Osteomyelitis of rib, sternum, clavicle, scapula, or vertebra.

21. Other symptomatic traumatic lesions of the chest or its contents.

22. Pleurisy with effusion, within the previous 2 years, unknown origin.

23. Pneumothorax during the year preceding examination if due to simple trauma or surgery; during the 3 years preceding examination if of spontaneous origin. Surgical correction is acceptable if no significant residual disease or deformity remains and pulmonary function tests are within normal limits. Recurrent spontaneous pneumothorax ipsilaterally is disqualifying regardless of cause, after one failed attempt at surgical correction or pleural sclerosis.

24. Sarcoidosis (See subsection JJ.12., below.)

25. Significant abnormal findings of the chest wall, lung(s), pleura or mediastinum.

26. Silicone injections, without encapsulation, in breasts for cosmetic purposes. Surgical placement of encapsulated implants is acceptable if a minimum of 9 months has elapsed since surgery and site is well-healed with no complications reported.

27. Suppurative periostitis of rib, sternum, clavicle, scapula, or vertebra.

28. Tuberculous lesions (See subsection JJ.14., below.)

29. Unhealed recent fracture of ribs, sternum, clavicle, or scapula, or unstable fracture regardless of fracture age.

V. MOUTH

The causes for rejection for appointment, enlistment, and induction are:

1. Hard palate, perforation of.

2. Cleft lip, unless satisfactorily repaired by surgery.

3. Leukoplakia, stomatitis or ulcerations of the mouth, if severe.

4. Ulcerations, perforation, or extensive loss of substance of the hard or soft palate, extensive adhesions of the soft palate to the pharynx, or complete paralysis of the soft palate. Unilateral paralysis of the soft palate that does not interfere with speech or swallowing and is otherwise asymptomatic is not disqualifying. Loss of the uvula that does not interfere with speech or swallowing is not disqualifying.

W. NOSE AND SINUSES

The causes for rejection of appointment, enlistment, and induction are:

1. Allergic Manifestations

a. Atrophic rhinitis.

b. Allergic Rhinitis. If moderate or severe and not controlled by oral medications, desensitization, or topical corticosteroid medication.

2. Anosmia or parosmia.

3. Choana, atresia or stenosis of, if symptomatic.

4. Epistaxis, chronic recurrent.

5. Nasal polyps or a history of nasal polyps, unless surgery was performed at least 1 year before examination and there is no evidence of recurrence.

6. Nasal septum, perforation of:

a. Associated with the interference of function, ulceration, crusting, or when the result of organic disease.

b. If progressive.

c. If respiration is accompanied by a whistling sound.

7. Sinusitis. Acute.

8. Sinusitis. Chronic when more than mild:

a. Evidenced by any of the following: chronic purulent nasal discharge, nasal polyps, hyperplastic changes of the nasal tissue, or symptoms requiring frequent medical attention.

b. Confirmed by transillumination or x-ray examination or both.

9. Vasomotor rhinitis, If moderate or severe and not controlled by medication.

X. PHARYNX, TRACHEA, AND LARYNX

The causes for rejection for appointment, enlistment, and induction are:

1. Laryngeal paralysis, sensory or motor, due to any cause.

2. Larynx, organic disease of, such as neoplasm, polyps, granuloma, ulceration, or chronic laryngitis.

3. Dysphonia Plicae Ventricularis.

4. Tracheostomy or tracheal fistula.

Y. OTHER DEFECTS AND DISEASES OF THE MOUTH, NOSE, THROAT, PHARYNX AND LARYNX

The causes for rejection for appointment, enlistment, and induction are:

1. Aphonia, or history of, or recurrent, if the cause was such as to make a subsequent attack probable.

2. Deformities or conditions of the mouth, tongue, throat, pharynx, larynx, and nose that interfere with mastication and swallowing of ordinary food, or with speech or breathing.

3. Destructive syphilitic disease of the mouth, nose, throat, or larynx. (See section MM., below.)

4. Pharyngitis and nasopharyngitis, chronic, with positive history and objective evidence, if of such a degree as likely to result in excessive time lost in the military environment.

z. NEUROLOGICAL DISORDERS

The causes for rejection for appointment, enlistment, and induction are:

1. Cerebrovascular Conditions. Any history of subarachnoid or intracerebral hemorrhage, vascular insufficiency, arteriovenous malformation, or aneurysm, whether transient or with secondary infarction involving the central nervous system.

2. Congenital malformations if associated with neurological manifestations or if the process is expected to be progressive; meningocele even if uncomplicated.

3. Degenerative and hereditodegenerative disorders affecting the cerebrum, basal ganglia, cerebellum, spinal cord, peripheral nerves or muscles.

4. Recurrent headaches, of all types of sufficient severity or frequency as to interfere with normal function or a history of such headaches within 3 years.

5. Head Injury

a. Applicants with a history of head injury are unacceptable at any time if they display any of the following:

(1) Late post-traumatic epilepsy (occurring more than 1 week after injury).

(2) Permanent motor or sensory deficits.

(3) Impairment of intellectual function.

(4) Alteration of personality.

(5) Central nervous system shunt of any type.

b. Applicants with a history of severe head injury are unfit for a period of at least 5 years after which they may be considered fit if complete neurological and neuropsychological evaluation (see Table 1) shows no residual dysfunction or complications. Severe head injuries are defined by one or more of the following:

(1) Unconsciousness or amnesia, alone or in combination, of 24 hours duration or longer.

(2) Depressed skull fracture.

(3) Laceration or contusion of dura or brain.

(4) Epidural, subdural, subarachnoid, or intracerebral hematoma.

(5) Associated abscess or meningitis.

(6) Cerebrospinal fluid rhinorrhea or otorrhea persisting more than 7 days.

(7) Focal neurologic signs.

(8) Radiographic evidence of retained metallic or bony fragments.

(9) Leptomeningeal cysts or arteriovenous fistula.

(10) Early post-traumatic seizure(s) occurring within 1 week of injury but more than 30 minutes after injury.

c. Applicants with a history of moderate head injury are unfit for a period of at least 2 years after which they may be considered fit if complete neurological evaluation (see Table 1) shows no residual dysfunction or complications. Moderate head injuries are defined as unconsciousness or amnesia, alone or in combination, of 1 to 24 hours duration or linear skull fracture.

d. Applicants with a history of mild head injury as defined by a period of unconsciousness or amnesia, alone or in combination, of 1 hour or less are unfit for at least 1 month after which they may be acceptable if neurological evaluation (see Table 1) shows no residual dysfunction or complications.

e. Persistent post-traumatic sequelae, as manifested by headache, vomiting, disorientation, spatial disequilibrium, personality changes, impaired memory, poor mental concentration, shortened attention span, dizziness, altered sleep patterns, or any findings consistent with organic brain syndrome, are disqualifying until full recovery has been confirmed by complete neurological and neuropsychological evaluation.

TABLE 1

EVALUATION FOR RISK OF HEAD INJURY SEQUELAE

DEGREE OF HEAD INJURY	MINIMUM OBSERVATION TIME	EVALUATION REQUIREMENTS
MILD (paragraph 2.5.d., above.)	1 MONTH	COMPLETE NEUROLOGICAL EXAMINATION BY A PHYSICIAN
MODERATE (paragraph 2.5.c., above.)	2 YEARS	COMPLETE NEUROLOGICAL EVALUATION BY A NEUROLOGIST OR INTERNIST CT SCAN
SEVERE (paragraph 2.5.b., above.)	5 YEARS FOR CLOSED HEAD TRAUMA 10 YEARS FOR PENETRATING HEAD TRAUMA	COMPLETE NEUROLOGICAL EVALUATION BY A NEUROLOGIST OR NEUROSURGEON CT SCAN NEUROPSYCHOLOGICAL EVALUATION

6. Infectious Diseases

a. Meningitis, encephalitis, or poliomyelitis within 1 year before examination, or if there are residual neurological defects that would interfere with satisfactory performance of military duty.

b. Neurosyphilis of any form (general paresis, tabes dorsalis, meningovascular syphilis).

7. Narcolepsy, Cataplexy, Sleep Apnea Syndrome (see paragraph kk19, page 1-50), and similar states except that sleep paralysis is not disqualifying by itself.

8. Paralysis, tremor or weakness, deformity, discoordination, pain, sensory disturbance, intellectual deficit, disturbances of consciousness, or personality abnormalities regardless of cause if there is any indication that such involvement is likely to interfere with prolonged normal function in any practical manner or is progressive or recurrent.

9. All forms of generalized or partial epilepsy that have persisted beyond the age of 5 unless the applicant has been free of seizures for a period of 5 years immediately preceding examination for military service while taking no medication for seizure control and has a normal electroencephalogram (EEG). All such cases will be referred to the Surgeon General's Office of the Service to which the individual is applying for determination of fitness. Documentation must include an original EEG taken within 3 months, a current neurology consultation containing details of the epileptic history, and an assessment of the present neurological status.

10. Any substantiated history of acquired chronic or recurrent disorders such as myasthenia gravis, polymyositis, and multiple sclerosis.

11. Central nervous system shunts of all kinds.

(Diagnostic concepts and terms used in the following section are in consonance with the Diagnostic and Statistical Manual, American Psychiatric Association, DSM-III-R, 1987.)

AA. DISORDERS WITH PSYCHOTIC FEATURES

The cause for rejection for appointment, enlistment, and induction is a history of a mental disorder with gross impairment in reality testing. This does not include transient disorders associated with intoxication, severe stress or secondary to a toxic, infectious, or other organic process.

BB. MOOD DISORDERS

The causes for rejection for appointment, enlistment, and induction are symptoms, diagnosis, or history of a major mood disorder requiring maintenance treatment or hospitalization.

CC. ANXIETY, SOMATOFORM, DISSOCIATIVE, OR FACTITIOUS DISORDERS (Alternatively may be addressed as Neurotic Disorders.)

The causes for rejection for appointment, enlistment, and induction are:

1. History of such disorders resulting in any or all of the below:

a. Hospitalization.

b. Prolonged care by a physician or other professional.

c. Loss of time from normal pursuits for repeated periods even if of brief duration.

d. Symptoms or behavior of a repeated nature that impaired social, school, or work efficiency.

2. History of an episode of such disorders within the preceding 12 months that was sufficiently severe to require professional attention or absence from work or school for more than a brief period (maximum of 7 days).

DD. PERSONALITY, BEHAVIOR, OR ACADEMIC SKILLS DISORDERS

The causes for rejection for appointment, enlistment, and induction are:

1. Personality or behavior disorders, as evidenced by frequent encounters with law enforcement agencies, antisocial attitudes or behavior that, while not sufficient cause for administrative rejection, are tangible evidence of impaired characterological capacity to adapt to military service.

2. Personality or behavior disorders where it is evident by history, interview, or psychological testing that the degree of immaturity, instability, personality inadequacy, impulsiveness, or dependency will seriously interfere with adjustment in the Armed Forces as demonstrated by repeated inability to maintain reasonable adjustment in school, with employers and fellow workers, and other social groups.

3. Other behavior problems including but not limited to conditions such as authenticated evidence of functional enuresis or encopresis, not due to an organic condition (see subsection M.2., above), sleepwalking, or eating disorders that are habitual or persistent, occurring beyond age 12, or stammering or stuttering of such a degree that the individual is normally unable to express himself or herself clearly or to repeat commands.

4. Specific Academic Skills Defects. Chronic history of academic skills or perceptual defects secondary to organic or functional mental disorders that interfere with work or school after age 12. Current use of medication to improve or maintain academic skills (e.g., methylphenidate hydrochloride) is disqualifying.

5. Suicide. History of attempted suicide or other suicidal behavior.

EE. PSYCHOSEXUAL CONDITIONS

The causes for rejection for appointment, enlistment, and induction are:

1. Transsexualism and other gender identity disorders.

2. Exhibitionism, Transvestism, Voyeurism and other paraphilias.

FF. SUBSTANCE MISUSE

The causes for rejection for appointment, enlistment, and induction are:

1. Alcohol dependence or history of.

2. Drug dependence or history of.

3. Drug abuse characterized by:

a. The evidence of use of any controlled, hallucinogenic, or other intoxicating substance at time of examination, when the use cannot be accounted for as the result of the advice of a recognized healthcare practitioner.

b. Documented misuse or abuse of any controlled substance (including cannabinoids or anabolic steroids) requiring professional care within a 1-year period before examination. Use of marijuana or other cannabinoids (not habitual use) or experimental or casual use of other drugs short of dependence may be waived by competent authority as established by the respective Armed Forces if there is evidence of current drug abstinence and the individual is otherwise qualified for service.

c. The repeated self-procurement and self-administration of any drug or chemical substance, including cannabinoids or anabolic steroids, with such frequency that it appears that the applicant has accepted the use of or reliance on these substances as part of his or her pattern of behavior. (See also appropriate Armed Forces instructions.)

4. Alcohol Abuse. Use of alcoholic beverages that leads to misconduct, unacceptable social behavior, poor work or academic performance, impaired physical or mental health, lack of financial responsibility, or a disrupted personal relationship. (See also appropriate Armed Forces instructions.)

GG. SKIN AND CELLULAR TISSUES

The causes for rejection for appointment, enlistment, and induction are:

1. Acne. Severe, or when extensive involvement of the neck, shoulders, chest, or back would be aggravated by or interfere with the wearing of military equipment and not amenable to treatment. Patients under treatment with isotretinoin (Accutane) are medically unacceptable until 8 weeks after completion of a course of therapy.

2. Atopic Dermatitis. With active or residual lesions in characteristic areas (face, neck, antecubital and/or popliteal fossae, occasionally wrists and hands), or documented history thereof after the age of 5.

3. Contact Dermatitis, involving rubber or other materials used in any type of required protective equipment.

4. Cysts

a. Cysts, Other Than Pilonidal. Of such a size or location as to interfere with the normal wearing of military equipment.

b. Cysts, Pilonidal. Pilonidal cysts, if evidenced by the presence of a tumor mass or a discharging sinus. History of pilonidal cystectomy within 1 year before examination is disqualifying.

5. Dermatitis Factitia.

6. Dermatitis Herpetiformis.

7. Eczema. Any type that is chronic and resistant to treatment.

8. Elephantiasis or Chronic Lymphedema.

9. Epidermolysis Bullosa.

10. Fungus infections, systemic or superficial types, if extensive and not amenable to treatment.

11. Furunculosis. Extensive, recurrent, or chronic.

12. Hyperhidrosis of Hands or Feet. Chronic or severe.

13. Ichthyosis. Severe.

14. Keloid Formation. If the tendency is marked or interferes with the wearing of military equipment.

15. Leprosy. Any type.

16. Leukemia Cutis: Mycosis Fungoides, Hodgkin's Disease. (See subparagraph LL.2.k.(1)(b), below, for additional remarks on Hodgkin's disease and the potential for service qualification.)

17. Lichen Planus

18. Neurofibromatosis (Von Recklinghausen's disease).

19. Nevi or vascular tumors, if extensive, interfere with function, or exposed to constant irritation.

20. Pemphigus or Pemphigoid.

21. Photosensitivity. Any primary sun-sensitive condition, such as polymorphous light eruption or solar urticaria; any dermatosis aggravated by sunlight such as lupus erythematosus.

22. Psoriasis or a verified history thereof.

23. Radiodermatitis.

24. Scars that are so extensive, deep, or adherent that they may interfere with the wearing of military clothing or equipment, exhibit a tendency to ulcerate, or interfere with function. Includes scars at skin graft donor or recipient sites if in an area susceptible to trauma.

25. Scleroderma (see paragraph JJ.7., below.)

26. Tattoos that will significantly limit effective performance of military service.

27. Urticaria. Chronic.

28. Warts, plantar, that have materially interfered with a useful vocation in civilian life.

29. Xanthoma, if disabling or accompanied by hyperlipemia.

30. Any other chronic skin disorder of a degree or nature that requires frequent outpatient treatment or hospitalization, or interferes with the satisfactory performance of duty.

HH. SPINE AND SACROILIAC JOINTS. (See also section I., above.)

The causes for rejection for appointment, enlistment, and induction are:

1. Arthritis. (See subsection I.1., above.)

2. Complaint of a disease or injury of the spine or sacroiliac joints with or without objective signs that has prevented the individual from successfully following a physically active vocation in civilian life. Substantiation or documentation of the complaint without objective physical findings is required.

3. Deviation or curvature of spine from normal alignment, structure, or function if:

a. It prevents the individual from following a physically active vocation in civilian life.

b. It interferes with the wearing of a uniform or military equipment.

c. It is symptomatic and associated with positive physical finding(s) and demonstrable by x-ray.

d. There is lumbar scoliosis greater than 20 degrees, thoracic scoliosis greater than 30 degrees and kyphosis or lordosis greater than 55 degrees when measured by the Cobb Method.

4. Diseases of the lumbosacral or sacroiliac joints of a chronic type associated with pain referred to the lower extremities, muscular spasm, postural deformities, or limitation of motion in the lumbar region of the spine.

5. Fusion involving more than two vertebrae. Any surgical fusion is disqualifying.

6. Granulomatous diseases either active or healed.

7. Healed Fractures or Dislocations of the Vertebrae. A compression fracture involving less than 25 percent of a single vertebra is not disqualifying if the injury occurred more than 1 year before examination and the applicant is asymptomatic. A history of fractures of the transverse or spinous processes is not disqualifying if the applicant is asymptomatic.

8. Juvenile Epiphysitis with any degree of residual change indicated by x-ray or kyphosis.

9. Ruptured Nucleus Pulposus (herniation of intervertebral disk) or history of operation for this condition.

10. Spina Bifida when symptomatic, or there is more than one vertebra involved, dimpling of the overlying skin, or a history of surgical repair.

11. Spondylolysis that is symptomatic or likely to interfere with performance of duty or limit assignments is disqualifying, even if successfully fused.

12. Weak or painful back requiring external support; that is, corset or brace. Recurrent sprains or strains requiring limitation of physical activity or frequent treatment.

13. Spondylolisthesis.

II. SCAPULAE, CLAVICLES, AND RIBS. (See section I., above.)

The causes for rejection for appointment, enlistment, and induction are:

1. Fractures, until well-healed, and until determined that the residuals thereof will not prevent the satisfactory performance of military duty.

2. Injury within the preceding 6 weeks, without fracture or dislocation, of more than a minor nature.

3. Osteomyelitis.

4. Prominent scapulae interfering with function or with the wearing of a uniform or military equipment.

JJ. SYSTEMIC DISEASES

The causes for rejection for appointment, enlistment, and induction are:

1. Amyloidosis.

2. Ankylosing Spondylitis.

3. Eosinophilic Granuloma. Eosinophilic granuloma, when occurring as a single localized bony lesion and not associated with soft tissue or other involvement, should not be a cause for rejection once healing has occurred. All other forms of the Histiocytosis X spectrum should be rejected, however.

4. Lupus Erythematosus.

5. Mixed Connective Tissue Disease.

6. Polymyositis/Dermatomyositis Complex.

7. Progressive Systemic Sclerosis, Including CREST Variant. A single plaque of localized scleroderma (morphea) that has been stable for at least 2 years is not disqualifying.

8. Psoriatic Arthritis.

9. Reiter's Disease.

10. Rheumatoid Arthritis.

11. Rhabdomyolysis, or history thereof.

12. Sarcoidosis, unless there is substantiated evidence of a complete spontaneous remission of at least 2 years duration.

13. Sjogren's Syndrome.

14. Tuberculosis.

a. Active tuberculosis in any form or location, or substantiated history of active tuberculosis within the previous 2 years.

b. Substantiated history of one or more reactivations or relapses of tuberculosis in any form or location or other definite evidence of poor host resistance to the tubercle bacillus.

c. Residual physical or mental defects from past tuberculosis that would prevent the satisfactory performance of duty.

d. Individuals with a past history of active tuberculosis MORE than 2 years before enlistment, induction, and appointment are NOT DISQUALIFIED provided they have received a complete course of standard chemotherapy for tuberculosis. In addition, individuals with a tuberculin reaction 10mm or greater and without evidence of residual disease in pulmonary or non-pulmonary sites are eligible for enlistment, induction, and appointment provided they have or will be treated with chemoprophylaxis in accordance with the guidelines of the American Thoracic Society and U.S. Public Health Service.

15. Vasculitis (Bechet's, Wegener's granulomatosis, polyarteritis nodosa).

KK. GENERAL AND MISCELLANEOUS CONDITIONS AND DEFECTS

The causes for rejection for appointment, enlistment, and induction are:

1. Allergic Manifestations. A reliable history of life-threatening generalize reaction with anaphylaxis to stinging insects. Reliable history of a moderate to severe reaction to common foods, spices or food additives.

2. Any acute pathological condition, including acute communicable diseases, until recovery has occurred without sequelae.

3. Any deformity, abnormality, defect, or disease that impairs general functional ability to such an extent as to prevent satisfactory performance of military duty.

4. Chronic metallic poisoning, especially beryllium, manganese, and mercury. Undesirable residuals from lead, arsenic, or silver poisoning make the applicant unacceptable.

5. Cold injury, residuals of, such as frostbite, chilblain, immersion foot, trench foot, deep-seated ache, paresthesia, hyperhidrosis, easily traumatized skin, cyanosis, amputation of any digit, or ankylosis.

6. Cold urticaria and angioedema, hereditary angioedema.

7. Filariasis: Trypanosomiasis, Amebiasis, Schistosomiasis, Uncinariasis (hookworm) associated with anemia, malnutrition, etc., or other similar worm or animal parasitic infestations, including the carrier states thereof, if more than mild.

8. Heat Pyrexia (heatstroke, sunstroke, etc.). Documented evidence of a predisposition (including disorders of sweat mechanism and a previous serious episode), recurrent episodes requiring medical attention, or residual injury resulting therefrom (especially cardiac, cerebral, hepatic, and renal).

9. Industrial solvent and other chemical intoxication, chronic, including carbon disulfide, trichloroethylene, carbon tetrachloride, and methyl cellosolve.

10. Malignant Hyperthermia.

11. Motion Sickness. An authenticated history of frequent, incapacitating motion sickness after the 12th birthday is disqualifying. For entrance into military academies or ROTC scholarship programs, admission of frequent, incapacitating motion sickness will suffice for disqualification.

12. Mycotic infection of internal organs.

13. Myositis or Fibrositis, severe, chronic.

14. Organ transplant recipient.

15. Presence of HIV-I or Antibody. Presence is confirmed by repeatedly reactive Enzyme-Linked Immunoassay serological test and positive immunoelectrophoresis (Western Blot) test, or other Food and Drug Administration-approved confirmatory test.

16. Reactive tests for syphilis such as the RPR or VDRL followed by a reactive, confirmatory Fluorescent Treponemal Antibody Absorption (FTA-ABS) test unless there is a documented history of adequately treated syphilis. In the absence of clinical findings, the presence of reactive RPR or VDRL followed by a negative FTA-ABS test is not disqualifying if a cause for the false positive reaction can be identified and is not otherwise disqualifying or if the test reverts to a non-reactive status during an appropriate followup period (3 to 6 months).

17. Residual of tropical fevers and various parasitic or protozoal infestations that, in the opinion of the medical examiner, prevent the satisfactory performance of military duty.

18. Rheumatic Fever during the previous 2 years, or any history of recurrent attacks; Sydenham's chorea at any age.

19. Sleep apnea (obstructive sleep apnea or sleep disordered breathing) which causes daytime hypersomnolence or snoring that interferes with the sleep of others.

LL. TUMORS AND MALIGNANT DISEASES

The causes for rejection for appointment, enlistment, and induction are:

1. Benign Tumors

a. Benign tumors of the head or face that interfere with function or prevent the wearing of face or protective masks or a helmet.

b. Benign tumors of the eyes, ears, or upper airway that interfere with function.

c. Benign tumors of the thyroid or other neck structures such as to interfere with function or the wearing of a uniform or military equipment.

d. Benign tumors of the breast (male or female), chest, or abdominal wall that would interfere with military duty.

e. Benign tumors of the respiratory, gastrointestinal, genitourinary, or musculoskeletal systems that interfere with function or the wearing of a uniform or military equipment.

f. Benign tumors of the musculoskeletal system likely to continue to enlarge, be subjected to trauma during military service, or show malignant potential.

g. Benign tumors of the skin that interfere with function, have malignant potential, or interfere with military duty or the wearing of the uniform or military equipment.

h. Benign tumors of the central nervous system, or history of if likely to recur.

i. Benign tumors of the peripheral nerves that interfere with function, have malignant potential, or interfere with military duty or the wearing of the uniform or military equipment.

2. Malignant tumors diagnosed by accepted laboratory procedures, and even though surgically removed or otherwise treated, with exceptions as noted. (Individuals who have a history of childhood cancer and who have not received any surgical or medical cancer therapy for 5 years and are free of cancer will be considered, on a case by case basis, for acceptance into the Armed Forces. Applicants must provide complete information about the history and present status of their cancer.)

a. Malignant tumors of the auditory canal, eye, or orbit (see section J., above) or upper airway.

b. Malignant tumors of the breast (male or female).

c. Malignant tumors of the lower airway or lung.

d. Malignant tumors of the heart.

e. Malignant tumors of the gastrointestinal tract, liver, bile ducts, or pancreas.

f. Malignant tumors of the genitourinary system, male or female. Wilm's tumor and germ cell tumors of the testis treated surgically and/or with chemotherapy in childhood, after a 2-year disease-free interval off all treatment may be considered on a case by case basis for service.

g. Malignant tumors of the musculoskeletal system.

h. Malignant tumors of the central nervous system and its membranous coverings, unless 5 years postoperative, off treatment, without recurrence, and without otherwise disqualifying residuals of surgery or the original lesion.

i. Malignant tumors of the endocrine glands.

j. Malignant melanoma or history thereof. Other skin tumors such as basal cell and squamous cell carcinomas surgically removed are not disqualifying.

k. Malignant Tumors of the Hematopoietic System

(1) Lymphomatous Diseases

(a) Non-Hodgkin's Lymphoma (all types).

(b) Hodgkin's disease, Active or Recurrent. Hodgkin's disease treated with radiation therapy and/or chemotherapy and disease-free off treatment for 5 years may be considered for service. Large cell lymphoma will likewise be considered on a case-by-case basis after a 2-year disease-free interval off all therapy.

(2) Leukemias. All types, except acute lymphoblastic leukemia treated in childhood without evidence of recurrence.

(3) Multiple Myeloma.

MM. SEXUALLY TRANSMITTED DISEASES

In general, the finding of acute, uncomplicated venereal disease that can be expected to respond to treatment is not a cause for medical rejection for military service. The causes for rejection for appointment, enlistment, and induction are:

1. Chronic sexually transmitted disease that has not satisfactorily responded to treatment. The finding of a positive serologic test for syphilis following adequate treatment is not in itself considered evidence of chronic venereal disease. (See section KK., above.)

2. Complications and permanent residuals of sexually transmitted disease when they are progressive, or of such a nature as to interfere with the satisfactory performance of duty, or are subject to aggravation by military service.

3. Neurosyphilis. (See section Z., above.)

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TITL: DODD 6485.1 Human Immunodeficiency Virus-1 (**HIV**-1), March 19, 1991 ASD(HA)

Ref: (a) Deputy Secretary of Defense Memorandum, "Policy on Identification, Surveillance, and Administration of Personnel Infected with Human Immunodeficiency Virus (**HIV**)," August 4, 1988 (hereby canceled)
(b) Deputy Secretary of Defense Memorandum "Recommendations for Revision of DoD Human Immunodeficiency Virus (**HIV**) Policies," March 8, 1988 (hereby canceled)
(c) Assistant Secretary of Defense (Health Affairs) Memorandum, "Policy on Clinical Evaluation, Staging and Disease Coding of Military Personnel Infected with Human Immunodeficiency Virus (**HIV**)," September 11, 1987 (hereby canceled)
(d) Assistant Secretary of Defense (Health Affairs) Memorandum, "The DoD HTLV-III Testing Program," December 5, 1985 (hereby canceled)
(e) through (p), see enclosure 1

A. PURPOSE

This Directive supersedes references (a) through (f) to update policy, responsibilities, and procedures on identification, surveillance, and administration of civilian and military personnel infected with **HIV**-1.

B. APPLICABILITY

This Directive applies to the Office of the Secretary of Defense, the Military Departments (including their Reserve components), the Chairman of the Joint Chiefs of Staff and the Joint Staff, the Unified and Specified Commands, and the Defense Agencies (hereafter referred to collectively as "the DoD Components"). The term "Military Services," as used herein, refers to the Army, the Navy, the Air Force, and the Marine Corps.

C. DEFINITIONS

1. Human Immunodeficiency Virus-1 (**HIV**-1). The virus most commonly associated with the Acquired Immune Deficiency Syndrome (AIDS) in the United States.

2. **HIV**-1 and/or AIDS Education Program. Any combination of information, education, and behavior-change strategies designed to facilitate behavioral alteration that will improve or protect health. Included are those activities intended to support or influence individuals in managing their own health through lifestyle decisions and self-care. Operationally, such programs include community, worksite, and clinical aspects using appropriate public health education methodologies.

3. Serologic Evidence of **HIV**-1 Infection. A reactive result given by a Food and Drug Administration (FDA)-approved enzyme-linked immunosorbent assay (ELISA) serologic test that is confirmed by a reactive and diagnostic immunoelectrophoresis test (Western blot (WB)) test on two separate samples.

4. Host Nation. A foreign nation to which DoD U.S. civilian employees are assigned to perform their official duties.

5. DoD Civilian Employees. Current and prospective DoD U.S. civilian employees including appropriated and nonappropriated fund personnel. This does not include members of the family of DoD civilian employees employees of, or applicants for, positions with contractors performing work for the

of, or applicants for, positions with contractors performing work for the Department of Defense, or their families.

6. Epidemiological Assessment. The process by which personal and confidential information on the possible modes of transmission of **HIV**-1 are obtained from an **HIV**-1 infected person. This information is used to determine if previous, present, or future contacts of the infected individual are at risk for infection with **HIV**-1 and to prevent further transmission of **HIV**-1.

D. POLICY

It is DoD policy to:

1. Deny eligibility for appointment or enlistment for Military Service to individuals with serologic evidence of **HIV**-1 infection.

2. Screen active duty (AD) and Reserve component military personnel periodically for serologic evidence of **HIV**-1 infection.

3. Refer AD personnel with serologic evidence of **HIV**-1 infection for a medical evaluation of fitness for continued service in the same manner as personnel with other progressive illnesses, as specified in DoD Directive 1332.18 (reference (g)). Medical evaluation shall be conducted in accordance with the standard clinical protocol, as described in enclosure 2. Individuals with serologic evidence of **HIV**-1 infection who are fit for duty shall not be retired or separated solely on the basis of serologic evidence of **HIV**-1 infection. AD personnel with serological evidence of **HIV** -1 infection or who are ELI 5A repeatedly reactive, but WB negative or indeterminate, shall be advised to refrain from donating blood.

4. Deny eligibility for extended AD (duty for a period of more than 30 days) to those Reserve component members with serologic evidence of **HIV**-1 infection (except under conditions of mobilization and on the decision of the Secretary of the Military Department concerned). Reserve component members who are not on extended AD or who are not on extended full-time National Guard duty, and who show serologic evidence of **HIV**-1 infection, shall be transferred involuntarily to the Standby Reserve only if they cannot be utilized in the Selected Reserve.

5. Retire or separate AD or Reserve Service members infected with **HIV**-1 who are determined to be unfit for further duty, as implemented in reference.

6. Ensure the safety of the blood supply through policies of the Armed Services Blood Program Office, the FDA guidelines, and the accreditation requirements of the American Association of Blood Banks.

7. Comply with applicable statutory limitations on the use of the information obtained from a Service member during, or as a result of, an epidemiological assessment interview and the results obtained from laboratory tests for **HIV**-1, as provided in this Directive. (See enclosure 3.)

8. Control transmission of **HIV**-1 through an aggressive disease surveillance and health education program.

9. Provide education and voluntary **HIV**-1 serologic screening for DoD healthcare beneficiaries (other than Service members).

10. Comply with host-nation requirements for **HIV**-1 screening of DoD civilian employees, as described in enclosure 8.

E. RESPONSIBILITIES

1. The Assistant Secretary of Defense (Health Affairs), in coordination with the Assistant Secretary of Defense (Force Management and Personnel) (ASD(FM&P)), the General Counsel of the Department of Defense (GC, DoD), and the Assistant Secretary of Defense (Reserve Affairs), is responsible for establishing policies, procedures, and standards for the identification, surveillance, and administration of personnel infected with **HIV**-1. The Assistant Secretary of Defense (Health Affairs) (ASD(HA)) shall provide overall policy guidance and approval for the **HIV**-1 and/or AIDS education and information efforts and shall establish the **HIV**-1 and/or AIDS Information and Education Coordinating Committee.

2. The Secretaries of the Military Departments shall establish Service policies, procedures, and standards for the identification, surveillance, education, and administration of personnel infected with **HIV**-1, based on and consistent with all sections of this Directive.

3. The Assistant Secretary of Defense (Force Management and Personnel) shall establish and revise policies governing **HIV**-1 screening of DoD civilian employees assigned to, performing official travel in, or deployed on ships with ports of call at host nations, in coordination with the ASD(HA), the Assistant Secretary of Defense (International Security Affairs), and the GC, DoD.

4. The Assistant Secretary of Defense (International Security Affairs) shall identify or confirm host-nation **HIV**-1 screening requirements for DoD civilians, transmit this information to the ASD(FM&P), and coordinate requests for screening with the Department of State.

5. The Heads of the DoD Components shall implement **HIV**-1 screening policies and procedures for DoD civilian employees identified in subsection E.3., above, and shall take the following actions:

a. Report newly established host-nation **HIV**-1 screening requirements to the ASD(FM&P) and provide sufficient background information to support a decision. This reporting requirement is exempt from licensing, in accordance with DoD 7750.5-M, paragraph E.4.b. (reference (h)).

b. Develop and distribute-policy implementing instructions.

c. Establish procedures to notify individuals who are evaluated as **HIV**-1 seropositive and provide initial counseling to them.

F. PROCEDURES

1. Applicants for Military Service and, periodically, AD and Reserve component military personnel shall be screened for serologic evidence of **HIV**-1 infection. Testing and interpretation of results shall be in accordance with the procedures in enclosure 4. Test results shall be reported to the Reportable Disease Data Base, as described in the ASD(HA) Memorandum (reference (i)).

2. Applicants for enlisted service shall be screened at the Military Entrance Processing Stations or the initial point of entry to Military Service. Applicants who enlist under a delayed enlistment program, but before entry on AD and who exhibit serologic evidence of **HIV**-1 infection, may be discharged due to erroneous enlistment.

3. Officer candidates shall be screened during their preappointment and/or precontracting physical examination. The disposition of officer applicants who are ineligible for appointment due to serologic evidence of **HIV**-1 infection shall be in accordance with the procedures in enclosure 5.

4. Applicants for Reserve components shall be screened during the normal entry physical examinations or in the preappointment programs established for officers. Those individuals with serologic evidence of **HIV**-1 infection who are required to meet accession medical fitness standards to enlist, or be appointed, are not eligible for Military Service with the Reserve components.

5. Initial testing and periodic retesting of AD and Reserve component personnel shall be accomplished in the priority listed in enclosure 6.

6. AD personnel (including Active Guard and/or Reserve) who exhibit serologic evidence of **HIV**-1 infection shall receive a medical evaluation in accordance with the procedures in enclosures 2, 6, and 7. Guard and Reserve personnel, not on extended AD, must obtain a medical evaluation from a civilian physician.

7. The Head of each Military Service shall appoint an **HIV**-1 and/or AIDS education program coordinator to serve as the focal point for all **HIV**-1 and/or AIDS education program issues and to integrate the educational activities of the medical and personnel departments.

8. An **HIV**-1 and/or AIDS Information and Education Coordinating Committee shall be established to enhance communication among the Military Services, recommend joint education policy and program actions, review education program implementation, and recommend methodologies and procedures for program evaluation. That committee shall be chaired by a representative of the ASD(HA). Members shall include two representatives from the Office of the ASD(FM&P) 4 and the **HIV**-1 and/or AIDS education program coordinator from each Military Service. Additional members shall represent the Armed Services Blood Program Office and, on an ad hoc basis, the OASD(HA). Policy and program proposals shall be coordinated with the Secretaries of the Military Departments.

9. The Head of each Military Service shall prepare a plan for the implementation of a comprehensive **HIV**-1 and/or AIDS education program that includes specific objectives with measurable action steps. The plan shall address information, education, and behavior-change strategies, as described in enclosure 6.

10. Civilians may not be mandatory tested for serologic evidence of **HIV**-1 infection except as necessary to comply with valid host-nation requirements for screening of DoD employees. Procedures for mandatory screening of DoD civilians shall be in accordance with enclosure 8.

11. The medical assessment of each exposure to, and/or case of, **HIV**-1 infection seen at a military medical treatment facility (MTF) shall include an epidemiological assessment of the potential transmission of **HIV** -1 to other persons at risk of infection, including sexual and other intimate contacts and family of the patient, and transfusion history. The occurrence of **HIV**-1 infection or serologic evidence of **HIV**-1 infection may not be used as a basis for any disciplinary action against an individual, except as described in enclosure 3.

12. Each military medical service shall conduct an ongoing clinical evaluation of each AD Service member with serologic evidence of **HIV**-1 infection at least annually. CD4 lymphocyte percentages or counts shall be monitored at least every 6 months. Appropriate preventive medicine counseling shall also be provided to all individual patients and public health education materials shall be made available to that medical services' beneficiary population. Each military medical service shall conduct longitudinal clinical evaluations of AD Service members with serologic evidence of **HIV**-1 infection and shall prepare internal reports

serologic evidence of **HIV**-1 infection and shall prepare internal reports to facilitate timely review and reassessment of current policy guidelines.

13. All military MTFs shall notify promptly the cognizant military health authority, when there is clinical or laboratory evidence indicative of infection with **HIV**-1 in accordance with enclosure 9.

14. The Secretary of each Military Department shall ensure that a mechanism is established to gather data on the epidemiology of **HIV**-1 infection of its members. Such epidemiological research shall be accomplished to ensure appropriate protection of information given by the Service member on the means of transmission.

15. The Department of the Army, as the lead Agency for infectious disease research within the Department of Defense, shall budget for and fund tri-Military Department DoD **HIV**-1 research efforts, in accordance with guidance provided by the ASD(HA). The research program shall focus on the epidemiology and natural history of **HIV**-1 infections in military and military associated populations; on improving the methods for rapid diagnosis and patient evaluation; and on studies of the immune response to **HIV**-1 infection, including the potential for increased risk in the military operational environment.

16. Service members with serologic evidence of **HIV**-1 infection shall be assigned within the United States, including Alaska, Hawaii, and Puerto Rico, due to the high priority assigned to the continued medical evaluation of military personnel. The Secretaries of the Military Departments may restrict such individuals to nondeployable units or positions for purposes of force readiness. To protect the health and safety of Service members with serologic evidence of **HIV**-1 infection and of other Service members (and for no other reason), the Secretaries of the Military Departments may, on the basis of an evaluation consistent with established Services procedures for other medical conditions, limit assignment of **HIV**-1-infected individuals on the nature and location of the duties performed in accordance with operational requirements.

17. AD and Reserve component personnel with serologic evidence of **HIV**-1 infection shall be retained or separated in accordance with enclosure 10.

18. The ASD(HA) shall issue policy guidance on the prevention of **HIV**-1 transmission to patients during exposure-prone invasive procedures, in coordination with the Heads of the Military Services, shall revise enclosures 2, 4, 6, and 7, as appropriate. The ASD(FM&P) shall revise enclosure 8, as appropriate. Revisions under this subsection shall be in coordination with the GC, DoD.

G. EFFECTIVE DATE AND IMPLEMENTATION

This Directive is effective immediately. Forward two copies of implementing documents to the Assistant Secretary of Defense (Health Affairs) within 90 days.

Donald J. Atwood Deputy Secretary of Defense

Enclosure - 10 1. References 2. Standard Clinical Protocol 3. Limitations on the Use of Information 4. **HIV**-1 Testing and Interpretation of Results 5. Administration of Officer Applicants 6. Disease Surveillance and Health Education 7. Procedure for Evaluating T-Helper Cell Count 8. **HIV**-1 Testing of DoD Civilian Employees 9. Personnel Notification and Epidemiological Investigation 10. Retention and Separation

REFERENCES, continued

(e) Assistant Secretary of Defense (Health Affairs) Memorandum, "Military

(e) Assistant Secretary of Defense (Health Affairs) Memorandum, "Military Implementation of Public Health Service Provisional Recommendations Concerning Testing Blood and Plasma for Antibodies to HTLV-III," July 17, 1985 (hereby canceled)
(f) DoD Instruction 1438.4, "Compliance with Host Nation Human Immunodeficiency Virus (**HIV**) Screening Requirements for DoD Civilian Employees," December 5, 1988 (hereby canceled)
(g) DoD Directive 1332.18, "Separation from the Military Service by Reason of Physical Disability," February 25, 1986
(h) DoD 7750.5-M, "DoD Procedures for Management of Information Requirements," November 1986, authorized by DoD Directive 7750.5, August 7, 1986
(i) Assistant Secretary of Defense (Health Affairs) Memorandum, "DoD Reportable Disease Database," December 30, 1985
(j) Chapter 47 of title 10, United States Code, "Uniform Code of Military Justice (UCMJ)"
(k) Assistant Secretary of Defense (Force Management and Personnel) Memorandum, "Information and Guidance on Human Immnunodeficiency Virus (**HIV**)," January 22, 1988
(l) Federal Personnel Manual Bulletin 792-42, "AIDS in the Workplace, March 24, 1988
(m) Section 794 of title 29, United States Code, "Section 504 of the Rehabilitation Act of 1973," as amended
(n) DoD Directive 5400.11, "Department of Defense Privacy Program," June 9, 1982
(o) Assistant Secretary of Defense (Health Affairs) Memorandum, "**HIV** Testing and Look Back Guidelines for Homologous Blood Donations," January 11, 1989
(p) Public Law 93-579, "Privacy Act of 1974," December 31, 1974 (5 U.S.C. 552a)

STANDARD CLINICAL PROTOCOL

A. MEDICAL EVALUATION

1. A complete medical evaluation shall be accomplished, at least annually, and T-cell subset evaluation at least every 6 months, on military personnel with serologic evidence of **HIV**-1 infection. This medical evaluation shall be documented in a manner consistent with the Head of the Medical Evaluation Board requirements of each Service.

2. Minimally, the medical workup shall include the following:

a. An epidemiological assessment.

b. History and physical examination, to include a neurological and neuropsychiatric evaluation.

c. Complete blood count with differential, platelet count, red blood cell indices, and erythrocyte sedimentation rate.

d. Total lymphocyte count, total T-lymphocyte cell count, and absolute CD4 and CD8 levels.

e. Intradermal skin tests (intermediate purified protein derivative standard tuberculin units, mumps 40 colony forming units (CFU) per milliliter (ml), trichophyton 1:30, candida 1:10, and tetanus 1:10).

f. **HIV**-1 ELISA and confirmation test.

g. Chest x-ray (posterior-anterior and lateral) on the initial evaluation. Subsequent chest x-rays shall be ordered when clinically indicated.

3. Because of the strong association of **HIV**-1 infection with other sex ually transmitted diseases, the workup minimally shall include evaluative tests for syphilis, hepatitis, urethritis, cervicitis, or proctitis.

4. The Surgeon General of each Military Department shall designate DoD Component military MTFs, which are to be used to evaluate and treat individuals with serologic evidence of **HIV**-1 infection. The initial evaluation and annual reevaluation of Service members with serologic evidence of **HIV**-1 infection shall ordinarily be accomplished within the individual's respective Military Department. In the case of symptomatic individuals, subsequent hospitalizations or continuation of care following the initial evaluation may be at any designated MTF within the Department of Defense.

5. A frozen blood specimen on all **HIV**-1-positive individuals shall be maintained for at least 3 years at -70 Celsius. The Military Departments shall maintain central serum banks.

6. A mental health assessment and social history shall be elicited that includes current emotional and social support, depression, interpersonal relationships, and work adjustment. Sociodemographic and psychosocial risk factors relating to suicide, drug and alcohol abuse, and major mental illness shall be emphasized. Subtle signs of dementia shall also be sought.

a. The mental health evaluation may be performed by a psychiatric nurse, psychiatric social worker, psychologist, trained nonpsychiatric physician, or psychiatrist, depending on local MTF resources.

b. Specific diagnostic and treatment modalities shall depend on clinical and research resources at each site, but may include psychiatric rating scales and behavioral intervention strategies. Examples of testing methods that shall be employed include the following: Beck Depression Index, Michigan Alcohol Screening Test, Perceived Social Support Questionnaire, Symptom Check List 90-Revised, Wechsler Memory Scale-Revised, Halstead-Reitan, and Trailmaking B.

c. Psychiatric consultation shall be sought for further evaluation, if concerns exist for fitness for duty, or if this screening evaluation suggests that more detailed psychiatric evaluation is needed. If the patient has persistent evidence of diminished intellectual skills, personality changes, and motor impairment, the patient shall require specialized studies (neurologic studies, computed tomography or magnet resonance imaging, lumbar puncture, psychiatric examination, and neuropsychologic testing) to evaluate the possible presence of a **HIV**-1-related mental or neurological syndrome.

B. ARMED FORCES **HIV**-1 DISEASE CLASSIFICATION

1. All patients with either serologic evidence of **HIV**-1 infection or a positive virus isolation shall be staged according to the following scheme:

Stage	**HIV**-1	Chronic	T-Helper	Delayed	Thrush	Oppor-
Antibody	Lymph-	Cells per	Hyper-		tunistic	
and/or	adenopathy	Cubic	sensi-		Infection	
Virus		Millimeter	tivity			
Isolation		(mm3)				
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