

FOIA MARKER

**This is not a textual record. This is used as an
administrative marker by the William J. Clinton
Presidential Library Staff.**

Collection/Record Group: Clinton Presidential Records

Subgroup/Office of Origin: National AIDS Policy Office

Series/Staff Member:

Subseries:

OA/ID Number: 21069

FolderID:

Folder Title:

Military [Folder 3]

Stack:

S

Row:

67

Section:

1

Shelf:

2

Position:

1

July 14, 2000

ADM James M. Loy
Commandant
United States Coast Guard
2100 Second Street, S.W.
Washington, DC 20593-0001

Re: Removal of HIV+ Persons from the TDRL

Dear ADM Loy:

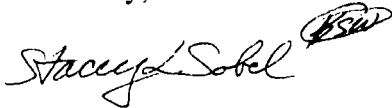
We write to ask that the Coast Guard temporarily halt all administrative actions related to the removal of HIV positive (HIV+) members from the Temporary Disability Retirement List (TDRL). The Defense Department (DoD), along with the Department of Veterans Affairs (VA), is studying the issue of HIV+ TDRL removal. As an interim measure, DoD has suspended removing further HIV+ members from the TDRL. We are enclosing letters from DoD concerning this matter for your review. We ask that the Coast Guard follow DoD's lead and, as an interim measure, refrain from further HIV TDRL removals pending DoD, Coast Guard and VA resolution.

The DoD recently proposed to VA to correct an outdated provision in the VA Schedule for Rating Disabilities (VASRD) regarding HIV disease. Many service members with HIV disease are at risk of losing access to the military health care and retirement systems if prompt action is not taken. The DoD's proposal to modify the VASRD standard for determining whether an HIV positive member is rated as 30 percent disabled is encouraging. We hope that the VA will quickly implement this proposal. More, however, must be done to assist service members whose needs are not addressed by the current DoD proposal.

The DoD proposal does not address two major concerns: (1) many HIV+ service members at risk of being removed from the TDRL will not benefit from this proposed VASRD modification; and (2) the question of how to handle those HIV+ personnel, and possibly their HIV infected family members, who have already been removed from the military's disability retirement system.

Servicemembers Legal Defense Network continues to discuss these issues with DoD and requests that the Coast Guard not separate HIV+ service members while these issues are still under review.

Sincerely,



Stacey L. Sobel, Esq.
Legal Director

Encl. 5

cc: The Honorable John F. Kerry, U.S. Senate

The Honorable Cynthia McKinney, U.S. House of Representatives
Ms. Julian Potter, Special Assistant to the President
✓ Ms. Sandra L. Thurman, Director of AIDS Policy, The White House
Mr. Matthew Murgia, Associate Director for Policy, Office of National AIDS Policy, The White House
Ms. Gail McGinn, DoD Force Management
RADM Robert Olsen, Director Coast Guard Personnel Management
CDR Francis Propst, Coast Guard Health and Safety Directorate
LCDR J.B. Nicholson, PDES Legal Division
Dr. Lawrence R. Deyton, VA Director, AIDS Services
Mr. Julia Abreu, AIDS Action Council
Ms. Tracey St. Pierre, Human Rights Campaign
Mr. William E. Emnett, Esq., Skadden Arps

Servicemembers Legal Defense Network

★ ★ ★ ★ ★

February 24, 2000

Dr. Sue Bailey
Assistant Secretary of Defense (Health Affairs)
1000 Defense Pentagon
Washington, D.C. 20301-1000

Mr. Alphonso Maldon, Jr.
Assistant Secretary of Defense (Force Management)
1000 Defense Pentagon
Washington, D.C. 20301-1000

Re: DoD Proposed VASRD Modification for HIV

Dear Dr. Bailey and Mr. Maldon:

We recently received a copy of the Defense Department proposal to the Department of Veterans Affairs (VA) to correct an outdated provision in the VA Schedule for Rating Disabilities (VASRD) regarding HIV disease. As the proposal notes, many service members with HIV disease are at risk of losing access to the military health care and retirement systems if prompt action is not taken. The proposal to modify the VASRD standard for determining whether an HIV positive member is rated as 30 percent disabled is encouraging. We hope that the VA will quickly implement this proposal.

This proposal, however, does not address two major concerns: (1) Many HIV positive service members at risk of being removed from the Temporary Disability Retirement List (TDRL) will not benefit from this proposed VASRD modification; and (2) The question of how to handle those HIV positive personnel, and possibly their HIV infected family members, who have already been removed from the military's disability retirement system should be addressed.

(1) Many HIV positive TDRL personnel who have never had fewer than 200 CD4 counts will continue to be unfairly removed from the military disability system. The VASRD provision for determining whether an HIV positive member is 30 percent disabled places a heavy emphasis on whether the patient has a CD4 count of less than 200.

As you are likely aware, the Services have not always applied the VASRD in determining HIV disability ratings. The Army, for example, used a CD4 count of 400 as its marker for determining whether an HIV positive member was at least 30 percent disabled.¹ Consequently, many HIV infected soldiers were placed on the TDRL after their CD4 counts dropped below 400. Many of these soldiers, however, have never had

¹ See U.S. Army Physical Disability Agency Policy Memorandum #9 – *Rating Guidance for Human Immunodeficiency Virus Infection*, 6 June 1995.

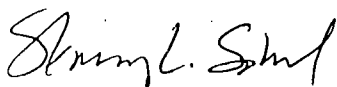
CD4 counts below 200 and would, therefore, most likely not benefit from this VASRD HIV disability rating proposal.²

Additionally, some of these HIV TDRL patients also have HIV positive family members who rely upon the military medical system for their life sustaining health care needs. Should the service members be removed from the military system, their family members would not be eligible for access to medical care through the VA system.

(2) Finally, we know that at least seven HIV positive soldiers have been removed from the military disability retirement system entirely³ since DoD began strictly applying the VASRD standard.⁴ Their removal from the TDRL, based upon an outdated provision of the VASRD, must be addressed. What's more, if any of these veterans have HIV infected family members, their family members are now ineligible for care in either the DoD or VA health care systems.

While we are pleased with the proposal to modify the VASRD, we also believe that those issues addressed above can be easily resolved. SLDN is available to work with you in finding a satisfactory resolution and would appreciate the opportunity to meet with you for a fuller discussion of the issue.

Sincerely,



Stacey L. Sobel, Esq.
Legal Director

cc: The Honorable John F. Kerry, U.S. Senate
The Honorable Cynthia McKinney, U.S. House of Representatives
Ms. Julian Potter, Special Assistant to the President
Ms. Sandra L. Thurman, Director of AIDS Policy, The White House
Dr. Lawrence R. Deyton, VA Director, AIDS Services
Mr. Julia Abreu, AIDS Action Council
Ms. Tracey St. Pierre, Human Rights Campaign
Mr. William E. Emnett, Esq., Skadden Arps

² According to conversations between SLDN and Infectious Disease personnel at Walter Reed Army Medical Center (WRAMC), Washington, D.C.

³ According to a Freedom of Information Act (FOIA) response received by SLDN, at least seven HIV TDRL members have been removed through WRAMC.

⁴ See U.S. Army PDA Memorandum *Implementation of the Revised DoD Directive 1332.18 and New DoD Instructions 1332.28 and 1332.39*, 13 May 1997.



OFFICE OF THE SECRETARY OF DEFENSE

1000 DEFENSE PENTAGON
WASHINGTON, DC 20301-1000



Honorable Joseph Thompson
Under Secretary for Benefits
Department of Veterans Affairs
810 Vermont Avenue, NW
Washington, DC 20420

FEB 14 2000

Dear Mr. Thompson:

On behalf of the Department of Defense, we urge the Department of Veterans Affairs to take prompt action to correct an outdated provision in the Veterans Administration Schedule for Rating Disabilities (VASRD) denying eligibility for disability retirement for a significant number of military members with advanced HIV disease.

Currently, 152 military members with advanced HIV disease are nearing their legal maximum five-year duration on the Temporary Disability Retirement List (TDRL). At this time, members not fit to return to duty must be separated from military service. Under law, if their disability ratings are less than 30% on the VASRD, they will be discharged without disability retirement or continued eligibility for DoD health care services. Because of some changes in their conditions brought about by Highly Active Anti-Retroviral Therapy (HAART), an innovative multiple drug regimen, many of these members will not qualify for the Permanent Disability Retirement List and will be separated without retirement benefits. This is due to the outdated VASRD standard for a 30% rating for HIV-related illness.

The VASRD standard for a 30% rating for HIV-related illness (38 CFR § 4.88b, code 6351) relies most heavily on the patient suffering a drop in T4 cell count below 200. Many members placed on the TDRL on this basis have now experienced improvement in T4 cell count because of HAART. But they remain very sick, with continuing immune system impairment, high vulnerability to opportunistic infections, heavy reliance on toxic and complex drug regimens, and dependence upon ongoing expert medical follow-up. As discussed further in the enclosure, the VASRD should be updated so that these members would be correctly recognized as continuing to have a degree of physical disability impairment equal to a 30% rating.

Sincerely,

Dr. Sue Bailey

Assistant Secretary of Defense for Health
Affairs

Sincerely,

Alphonso Maldon, Jr.

Assistant Secretary of Defense for Force
Management Policy

Enclosure

cc: Sandra L. Thurman, National AIDS Policy Director



DoD Proposed Correction of VASRD For HIV-Related Illness

Problem

Currently, 152 military members with HIV disease are nearing their legal maximum five-year duration on the Temporary Disability Retirement List, requiring that if they are not fit to return to duty they be separated from military service. Under law, if their disability ratings are less than 30% on the Veterans Administration Schedule for Rating Disabilities (VASRD), they will be discharged without disability retirement or continued eligibility for DoD health care services. Because of some changes in their conditions brought about by Highly Active Anti-Retroviral Therapy (HAART), an innovative multiple drug regimen, many of these members will not qualify for the Permanent Disability Retirement List and will be separated without retirement benefits. This is due to the outdated VASRD standard for a 30% rating for HIV-related illness.

Solution

The VASRD standard for a 30% rating for HIV-related illness (38 CFR § 4.88b, code 6351) should be revised as follows (change in *italics*):

Recurrent constitutional symptoms, intermittent diarrhea, and on approved medication(s), or: minimum rating with T4 cell count *at any time* less than 200, or Hairy Cell Leukoplakia, or Oral Candidiasis — 30%.

Under this change, HIV patients who have experienced improvement in T4 cell count because of HAART, would be correctly recognized as continuing to have a degree of physical disability impairment equal to a 30% rating.

Rationale

1. Current VASRD ratings fairly accurately reflect the disability of patients whose health deteriorated because no effective therapy yet existed at the time the schedule was created. The advent of Highly Active Anti-Retroviral Therapy (HAART), which dramatically altered the expected clinical course of this disease for many patients, has significantly complicated the assessment of HIV induced disease and disability. As a consequence, some patients, particularly those with advanced disease, may have their true disability significantly underestimated.

2. Even in the era of HAART, individuals with advanced HIV disease continue to have a clinical course that is very different from individuals with lesser severity disease. The immune system has been severely damaged, leaving the affected individual vulnerable to usually harmless environmental organisms (opportunistic infections). HAART, when successful, can stop the net loss of T4 cells halting further erosion of immune function. If therapy remains effective, the immune system begins to regenerate as demonstrated by increasing T4 cell numbers and increased resistance to opportunistic infections.

3. However, the patient with advanced HIV disease has perhaps six or more years of continuing immunologic impairment which may not be reflected in his T4 count. The reason that T4 cell counts alone do not adequately predict immune sufficiency in patients with advanced HIV disease is related to the nature of other damage done by HIV. In advanced disease, entire clones of lymphocytes with specialized functions, such as the protection against a particular microbe, are lost and with them that specialized function is also lost. HAART may be able to keep other clones from being lost but the lost clones must be regrown. The initial increases in T4 count that are measured following the initiation of HAART represent expansion of existing clones, not regrowth of the lost ones so immune function remains impaired. The process of regeneration takes time and the absolute number of T4 cells does not tell the whole story of how functional the immune system actually is. Furthermore, the process of regeneration is completely dependent upon maintaining control of the virus since a return of the "malady" would certainly doom the recovery of the immune system.

4. Viral control is far more difficult in advanced disease than in earlier stages because the patient's HIV has changed as well. There is more variability in the viral genetic structure owing to constant mutations and selective pressures from the host. This has a tendency to increase both the virus' resistance to the host's immune system as well as its pathogenicity. Because it usually has already been exposed to multiple anti-retroviral regimens, it is commonly resistant to at least some of the available regimens. This leads to the usual situation in patients with advanced disease who, despite favorable increases in their T4 count, continue to experience disability and increased likelihood of death. They are commonly on "salvage" regimens that are not only extremely complex but are very likely to have associated toxicity. These factors in combination increase the likelihood of therapeutic failure, which necessitates more frequent follow-up by subspecialty experts.

5. The end result is a patient with ongoing immune defects, who is on highly toxic, complicated regimens, and who needs frequent subspecialty physician monitoring for signs of failure and/or regimen adjustment. This patient continues to have a markedly increased probability of further disease and/or death, his life is directly impacted by unavoidable side-effects of his treatment and his constant medical care all conspire to make him disabled at a level of at least 30%.

Conclusion

The current VASRD's heavy reliance on T4 cell count is outdated, failing to correctly assess the degree of disability in patients who have through Highly Active Anti-Retroviral Therapy regained a T4 cell count over 200 but still suffer severe effects of advanced HIV disease. Without a correction to the VASRD, a large number of military members will soon be required by law to be separated without disability retirement benefits or continued military medical care. The VASRD should be corrected.

December 16, 1999

The Hon. Rudy de Leon
Under Secretary of Defense (Personnel and Readiness)
4000 Defense Pentagon
Washington, D.C. 20301-4000

Dear Secretary de Leon:

We write to renew our request that the Department of Defense immediately suspend processing of HIV+ members from the Temporary Disability Retired List (TDRL) and the military disability retirement system. Despite our past requests, we understand that the Army continues to process HIV+ TDRL members for separation by sending them to Physical Evaluation Boards (PEB) and the PEBs have ruled that HIV+ persons should be removed from the TDRL. We are very concerned that some HIV+ service members may be dropping through the cracks and the Department of Defense has not taken remedial steps to ensure their well-being.

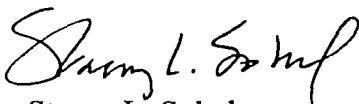
We understand that DoD is proposing revisions to the Veterans Affairs Schedule for Rating Disabilities (VASRD) in an effort to remedy the TDRL HIV removal problem. We appreciate this effort and would welcome a copy of the proposed revisions prior to their being sent to the Department of Veterans Affairs.

We also appreciate your understanding of the issues. In your August 20, 1999 letter to Sen. Kerry, you correctly acknowledged that this TDRL removal phenomena is the result of some HIV+ patients' favorable response to potent anti-retroviral therapy. You also correctly stated that "the durability of the response to combination anti-retroviral therapy is not certain. Twenty to fifty percent of patients are not able to maintain complete viral suppression and subsequently develop resistant HIV and increasing immunodeficiency."

We remain concerned, however, that removing HIV+ persons from the TDRL deprives them of the very comprehensive life sustaining medical treatments and protocols that are likely responsible for their "improved" immune responses. Given the unfortunate reality that the immune improvements in these HIV+ patients are probably artificially stimulated due to the large quantities of medications taken, their subsequent removal from the military disability retirement system raises serious concerns. Additionally, the emotional, physical and financial stress (as some have had to seek civilian legal representation) created by sending HIV+ TDRL members before these PEBs is unhealthy.

It has been almost six months since our initial request to stop processing HIV+ personnel for TDRL removal. We ask for your immediate assistance to correct this situation.

Sincerely,



Stacey L. Sobel
Senior Staff Attorney

cc: The Honorable John F. Kerry, United States Senate
The Honorable Cynthia McKinney, United States House of Representatives
Mr. Todd Sommers, Office of AIDS Policy, the White House
Mr. William E. Emmett, Esq., Skadden Arps
Ms. Tracey St. Pierre, Human Rights Campaign
Mr. Julio Abreu, AIDS Action Council



ASSISTANT SECRETARY OF DEFENSE
4000 DEFENSE PENTAGON
WASHINGTON, DC 20301-4000

AUG 26 1999

FORCE MANAGEMENT
POLICY

Honorable Cynthia A. McKinney
United States House of Representatives
Washington, DC 20515-1011

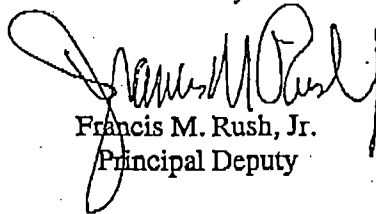
Dear Congresswoman McKinney:

Thank you for your letter concerning the Department's policy on HIV positive members in the military disability retirement system. I can assure you that we are evaluating every measure to ensure that disabled service members and their families are afforded the appropriate disability compensation for which they are eligible.

Under current statute, the Veterans Administration Schedule for Rating Disabilities (VASRD) is the required guide in the evaluation of disabilities resulting from all types of diseases and injuries encountered as a result of, or incident to, military service. Prior to March 1989, the Department applied the minimum 30 percent rating for HIV positive personnel. In March 1989, VASRD was updated to include the graduated disability-rating schedule for the HIV related illness. We are actively working possible solutions, including your suggestions, that would provide proper disability compensation for HIV positive members. In particular, we are developing an extensive change to the HIV rating in the VASRD that we will propose to the Department of Veterans Affairs (DVA) in the near term. Our intent is to ensure service members will not be denied retirement benefits warranted by their condition.

We appreciate your support for the men and women who serve in the Armed Forces.

Sincerely,



Francis M. Rush, Jr.
Principal Deputy





UNDER SECRETARY OF DEFENSE
4000 DEFENSE PENTAGON
WASHINGTON, D.C. 20301-4000

99 SEP -8 AM 4:33
AUG 20 1999

PERSONNEL AND
READINESS

Honorable John F. Kerry
United States Senate
Washington, DC 20510

Dear Senator Kerry:

Thank you for your letter stating concern about the removal of HIV positive members from the military disability retirement system. I assure you, we are actively working within the Department of Defense (DoD) to consider possible solutions to this problem, potentially including a proposal to the Department of Veterans Affairs (DVA) to modify the Veterans Administration Schedule for Rating Disabilities (VASRD) so that our service members will not be denied retirement benefits. Under the law, DoD is required to apply the VASRD.

Since the revision of Department of Defense Directive 6485.1, Human Immunodeficiency Virus-1, was issued in March 1991, there have been several significant changes in the clinical management of those individuals infected with the HIV virus. With the advent of potent anti-retroviral therapy, many service members on the Temporary Disability Retired List (TDRL) are experiencing significant clinical and immunologic improvements. During periodic evaluations of these members, increases in their T4 cell count are resulting in reduced disability ratings. If these individuals are removed from the TDRL with less than a 30% disability rating, they lose retirement benefits including medical treatment in DoD medical facilities for themselves and their family members. Unfortunately, the durability of the response to combination anti-retroviral therapy is not certain. Twenty to fifty percent of patients are not able to maintain complete viral suppression and subsequently develop resistant HIV and increasing immunodeficiency.

The Department is aware that the success of these new therapies will require a change to how we manage these service members in our disability retirement system. The Department is developing a request to the DVA for a change to the VASRD on the HIV disability rating to preclude these individuals from being denied disability retirement benefits. In the meantime, the military services are following individual cases so as to preclude precipitous action to separate HIV positive members from the TDRL.

We appreciate your support of the Department of Defense and look forward to working with you in the future.

Sincerely,

Rudy de Leon





18 May 2000

13 Taft Court

Suite 200

Rockville, Maryland

20850

Tel: 301-251-5000

Fax: 301-762-4177

Dear Colleagues:

Enclosed you will find a copy of the proceedings from the second Uganda Vaccine Workshop sponsored by the U.S. Military HIV Research Program titled *HIV Diagnostics and Genetic Variation in the Context of HIV Vaccine Studies*, held 30 September – 1 October 1999.

A third workshop, titled *Neutralizing Antibody and Prevention of Viral Infection: Implications for HIV Vaccine Development*, was just held 10 May 2000 in Kampala, Uganda. We will be preparing a report of this meeting for distribution as well.

I hope you find this report and future updates useful. The information is a resource regarding the on-going vaccine research and development efforts in Uganda.

Sincerely

Deborah L. Birx, M.D.
Director
U.S. Military HIV Research Program
301-251-5093
Fax: 301-762-4177
dbirx@hivresearch.org

Sincerely,

Hope all is well.

Debbi

Clinton Presidential Records Digital Records Marker

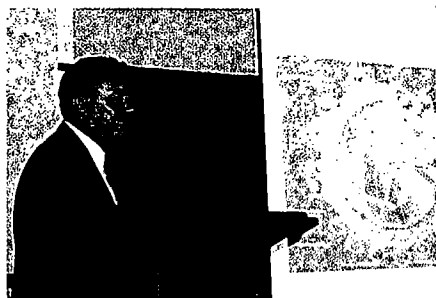
This is not a presidential record. This is used as an administrative marker by the William J. Clinton Presidential Library Staff.

This marker identifies the place of a publication.

Publications have not been scanned in their entirety for the purpose of digitization. To see the full publication please search online or visit the Clinton Presidential Library's Research Room.

Proceedings Uganda Vaccine Workshop

HIV Diagnostics and Genetic Variation in the Context of HIV Vaccine Studies



The Windsor Lake Victoria Hotel
Entebbe, Uganda
30 September – 1 October 1999





Mtg. Kelly Lenin
John Mascola
Debra Burks
Donna Ruscavage
Oct 15/11:00

1 Taft Court

Suite 250

Rockville, Maryland

20850

tel (301) 251-5000

fax (301) 294-1898

www.hjf.org

*Serving Military
Medicine Since 1983*

September 14, 1999

Sandra Thurman
Director
White House Office on National AIDS Policy
736 Jackson Place, NW
Washington, DC 20503

Dear Ms. Thurman,

It was a pleasure to meet you at the CDC's National HIV Prevention Conference in Atlanta. Per our discussion, I am forwarding a copy of the curriculum: *HIV Prevention and Behavior Change In International Military Populations*, as well as a copy of a presentation which summarizes the intervention. This intervention was developed collaboratively between the Civil-Military Alliance to Combat HIV and AIDS and the U.S. Military HIV Research Program, a cooperative effort of the Walter Reed Army Institute of Research and the Henry M. Jackson Foundation for the Advancement of Military Medicine.

We also talked about scheduling a visit to your office to brief you on the U.S. Military HIV Research Program's activities regarding behavioral research and program evaluation. I have enclosed some overview materials highlighting the Program. If additional information would be helpful, please contact me to extend an invitation to schedule an appointment.

On behalf of the U.S. Military HIV Research Program, thank you for your interest and I look forward to speaking with you soon.

Sincerely,

A handwritten signature in dark ink, appearing to read "DRuscavage".

Donna Ruscavage, MSW
Project Director

HIV Prevention Intervention Research
Department of Threat Assessment and Prevention Research
U.S. Military HIV Research Program

U.S. Military HIV Research Program

13 Taft Court
Suite 200
Rockville, Maryland 20850
(301) 294-1887
Fax: (301) 762-4177

Fax Cover Sheet

Date: 3 June, 1999
To: Todd Summers
Fax Number: 202-456-2438
From: Deborah Birx
Ext: 1149

Subject: Briefing Information

Total number of pages 4 **including this sheet**

Comments: Enclosed you will find the briefing information you requested. This was prepared by my office and is still being officially reviewed by the command. You should expect to receive an official version from the command, but the substance will be the same. If you prefer an e-mail version, please call Kelley Lennon at ext. 1072 and she can forward it to you.

Thank you.

DRAFT

INFORMATION PAPER

MCMR-PLA

2 June 1999

SUBJECT: DEPARTMENT OF DEFENSE (U.S. ARMY) HUMAN IMMUNODEFICIENCY VIRUS RESEARCH PROGRAM

BACKGROUND:

Human Immunodeficiency Virus (HIV), the virus responsible for AIDS, poses a significant threat to the U.S. Military. HIV infection is epidemic in almost every less well developed and potentially unstable region of the world, and the risk for exposure to HIV by DoD personnel is high. Over 19,000 new infections with HIV occur throughout the world each day. In response to this military-relevant infectious disease threat, a congressionally-mandated research program was begun in 1986 to assess and mitigate the impact on U.S. Military readiness by monitoring the spread of HIV infection in military forces and by developing methods to prevent infection. As lead agent for infectious disease research in DoD, the Army has a highly targeted program to address the military concerns of HIV: Surveillance of infection rates and HIV subtypes around the world; **development of vaccines** and other countermeasures to prevent infection; and clinical studies to avoid immune deficiency. The primary focus of this Program is the prevention of HIV infection in military personnel.

PROGRAM HIGHLIGHTS:

- HIV infection is relevant to today's military. Over 400 new infections occur annually in service members, with a significant number occurring during overseas deployments. This uniformly fatal disease also induces significant acute morbidity, which affects fighting readiness.
- The principal objective of the U.S. Military HIV Research Program is protection and preservation of the fighting force through primary prevention of HIV infection, **ultimately by administration of an effective, preventive vaccine.** *Success in achieving this goal will have broad-reaching application for HIV prevention in civilian populations worldwide.*

Currently, Program efforts focus on:

- 1) education of the force
- 2) surveillance and threat assessment, and
- 3) **a vigorous program of vaccine discovery, development, and evaluation.**

- The Program collaborates with multiple U.S. and international agencies and a network of DoD Overseas Biomedical Research Laboratories to provide an effective surveillance network to monitor the emergence of virological trends in the pandemic and to serve as permanent platforms for evaluation of candidate vaccines in overseas endemic settings.
- The Program has effectively leveraged its vaccine R&D funding and resources to pursue a number of novel candidate vaccine approaches and formulations. Extensive use of Cooperative Research and Development Agreements (CRADAs) with private industry greatly extends the resources of the U.S. Military HIV Research Program.

VACCINE R&D SUMMARY:

The U.S. Military HIV Vaccine Research and Development efforts augment and complement efforts of the DHHS. Domestic clinical trials of candidate vaccines based on the strains of HIV indigenous to the U.S. (genotype B) are conducted to gain familiarity with these novel constructs, to develop an initial safety database to facilitate transition of specific vaccine approaches for evaluation overseas with candidates specifically designed from the HIV viruses which circulate overseas, and, importantly, to harmonize (with the NIH) assays which are critical for evaluating the effects of vaccine candidates on the human immune system.

- Currently, three distinct classes of HIV vaccine candidates (recombinant subunit envelope, canarypox-vectored genes with subunit envelope boost, and facilitated plasmid DNA) are in clinical trials conducted by the U.S. Military HIV Vaccine Program. Clinical evaluation of these constructs is underway in the United States and Thailand. The focus of the Vaccine Development and Evaluation Program in the U.S. and Thailand is to select and then evaluate the most immunogenic of **safe candidate vaccines** for their ability to protect individuals from HIV infection. The current lead candidate is canarypox-vectored HIV (vCP1521) manufactured by Pasteur-Merrieux-Connaught, boosted by a recombinant subunit envelope (clade E, manufacturer TBD). Large-scale field efficacy testing is planned to begin in collaboration with the government of Thailand during 2001.
- Pre-clinical R&D of a number of novel candidates is being pursued by the Program, primarily through CRADAs with industry partners. In addition to small animal and macaque studies of novel immunogens (many of which are conducted under the auspices of an NIH contract as a simian vaccine evaluation unit), the U.S. Military HIV Research Program is poised to play a roll in the initial manufacture (by good manufacturing practices – GMP) of several of these new candidate vaccines. This is possible through the Walter Reed Army Institute of Research bioproduction facility at Forest Glen, Maryland. Currently, the Program plans to produce (with corporate partner AlphaVax and the International AIDS Vaccine Initiative) HIV particles based on the Venezuelan Equine Encephalitis replicon platform, and (with corporate partner AVANT Immunotherapeutics) recombinant anthrax antigen-vectored HIV core polypeptides which are called Therapore™HIV.

DRAFT

- Field efforts to prepare for large-scale testing of promising HIV candidate vaccines have been underway in Thailand since 1991. During this period, there has existed an effective alliance with multiple U.S. Government agencies (CDC, NIH, USAID). Efforts in collaboration with the Royal Thai Government have been extensive: national HIV surveillance, development of multiple field sites as potential venues for efficacy testing of promising candidates, creation of a phase I/II AIDS vaccine evaluation network at four academic and government sites, development of extensive in-country laboratory capability and technology transfer to conduct vaccine evaluations, and successful planning, implementation and completion of large multicenter human clinical trials. All vaccine development in Thailand is conducted with candidates incorporating elements of the indigenous Thai HIV (genotype E).
- More recent efforts, beginning last year, have focused on development of a similar field capability in collaboration with government and academic collaborations in Uganda. Vaccine development opportunities in Uganda are unique and complementary to other program efforts. Distinct genotypes of HIV (A and D) co-circulate in this region of the world. The ability to address efficacy and its breadth requires access to sites with such viral diversity. This is a critically important question to be answered in developing vaccines that will be effective for military populations. Again, close coordination with other U.S. Government agencies is envisioned, and will be critical to the success of U.S.-sponsored vaccine development efforts in Uganda.

AVAC "EIGHT YEARS AND COUNTING... WHAT WILL SPEED DEVELOPMENT OF AN AIDS VACCINE?"

In general, we find AVAC's assessments to be accurate. We believe we will be able to conduct a field efficacy trial in Thailand, as stated above. In regards to our pre-clinical activities, we are quite diverse; our resources must be spread in such a way as to avoid excessive risk and optimize our opportunities for development and evaluation of potentially improved future generation candidate vaccines.

A new initiative within the military infectious disease research program and the U.S. Army Medical Research and Materiel Command (of which this Program is one element) calls for annual external peer review – which may meet AVAC's suggestion for increased public input and scientific review.

Agency: DEPARTMENT OF DEFENSE – MILITARY

Heading: GENERAL PROVISIONS–DEPARTMENT OF DEFENSE

FY 2000 Budget
Appendix Page: 341

FY 2000
Pending Request: --

Proposed Amendment: -\$10,000,000

Revised Request: -\$10,000,000

(In the appropriations language under the above heading, insert the following new section immediately after section 8059.)

Sec. 8060. DISPOSAL OF ADDITIONAL MATERIALS. – (a) The President shall dispose of materials contained in the National Defense Stockpile Transaction Fund in addition to those otherwise authorized so as to result in additional receipts in the amount of \$10,000,000 by September 30, 2000. (b) The Secretary of Defense, as the President's designee, shall determine which additional materials will be available for sale. (c) The authority provided in subsection (a) is in addition to, and shall not affect, any other disposal authority provided by law. (d) Upon enactment of this Act, the Secretary of Defense shall transfer \$10,000,000 in balances from the National Defense Stockpile Transaction Fund to the "Defense Health Program" account. Such funds shall be available for HIV prevention educational activities undertaken in conjunction with U.S. military training, exercises, and humanitarian assistance activities conducted in African nations.

This new general provision would provide for additional sales of materials from the National Defense Stockpile Transaction Fund and for the transfer of \$10 million in balances from the Defense Stockpile to the Defense Health Program account, Operation and Maintenance. Balances transferred to the Defense Health Program would be used to conduct HIV prevention and education activities as part of DoD's ongoing training activities with African militaries.

This proposal would result in receipts in FY 2000 of \$10 million, which would offset the additional spending in the Defense Health Program account.

HIV Prevention Research in the U.S. Military HIV Research Program

Donna Ruscavage, MSW

CDR John Mascola

Department of Threat Assessment and Prevention Research

Presentation Goals

- 1) To increase understanding of the U.S. Military HIV Research Program's mission, structure and research initiatives
- 2) To describe current HIV prevention research activities within the Program and how they relate to HIV prevention work within the military services

U.S. Military HIV Research Program Overview

Overall Goal

To address the threat of HIV to military readiness, provide the best strategies to minimize the impact of the disease and to develop new diagnostic technologies to be used in the field

U.S. Military HIV Research Program

Strategic Objectives for Prevention of Military HIV Infections

- A. Demonstrate improved technology to transition to advanced development an immunization process to prevent infection and/or disease caused by all strains of HIV
- B. Provide technical data on the incidence, subtype and drug resistance pattern of incident HIV infection in the mobilization base and the active duty force

U.S. Military HIV Research Program

Strategic Objectives for Prevention of Military HIV Infections

- C. Provide technical data on the prevention and control of HIV infection to recommend improved personnel and training doctrine
- D. Provide unique cutting edge treatment options for the active force and beneficiaries

U.S. Military HIV Research Program Departments

Department of Vaccine Research identifies immune correlates of HIV protection and transmission and develops strategies for potential vaccine candidates

Department of Vaccine Development identifies and evaluates candidate vaccines capable of preventing HIV infection

U.S. Military HIV Research Program Departments

Department of Threat Assessment and Prevention Research provides technical data on HIV-1 diversity and global distribution, provides recommendations for improved training doctrine based upon field data and evaluates HIV prevention interventions

U.S. Military HIV Research Program Departments

Department of Clinical Studies and Interventions
conducts studies and early stage interventions and
collects data for natural history studies to more
completely understand HIV disease progression

U.S. Military HIV Research Program Departments

Department of Molecular Diagnostics and Pathogenesis provides diagnostic technical data on the incidence of HIV infections in the mobilization base and active duty force, develops field deployable HIV test kits and provides state of the art clinical management tools

Department of Threat Assessment and Prevention Research

Strategic Objective C:

Provide technical data on the prevention and control of HIV infection to recommend improved personnel and training doctrine

Department of Threat Assessment and Prevention Research

Specific Objective C5:

Evaluate efficacy of education/intervention strategies to recommend improved personnel and training doctrine

Department of Threat Assessment and Prevention Research

Approach to Specific Objective C5:

- 1) Transition of a Successful Skills-Building HIV/STD Intervention (SHIP)
- 2) Pilot Study of an HIV Prevention Interactive Video in the U.S. Army
- 3) Tri-Service Study of HIV Education and Prevention Needs in the U.S. Military (RV 128)
- 4) Pilot Study of a Modified Behavioral Intervention to Reduce HIV/STD Risk Behaviors

Prevention Research ➡

Objectives

- Assess risk of acquiring HIV infection
- Reduce high risk behavior
- Decrease new HIV/STD infections

STD/HIV Intervention Program

- Target to high risk situations and personnel
- Service specific resources e.g. NHRC, CHPPM
- Expert consultants

Risk Behavior Data

- Army-wide survey
- RV117 (tri-service)
- Unitas Cruise



Risk Assessment



Data

- High risk regions
- High risk deployments
- High risk activities

Target Interventions



Possible Future Interventions

- Tri-service Tech School
- Unitas cruise
- Cobra gold

Intervention Evaluation



Evaluation of effect

- Change of behavior
- Prove effectiveness on STD rates

modifications/
improvements



transition to
line activities



Current transitions

- Navy PMT school
- Marine SG training

Transition of a Skills-Building HIV/STD Intervention (SHIP)

Stephanie Brodine, MD, CDR Rick Shaffer,
Cherrie Boyer, PhD, Stephanie Kewley, PhD,
Rahn Minagawa, PhD, Patricia Gilman, MA,
Chief Paul Johnson, Paul Purnell, MS,
Donna Ruscavage, MSW, CDR John Mascola

Goals of Intervention

- Increase knowledge of Marine Security Guards about the transmission, prevention and medical outcomes of STDs/HIV prior to deploying to embassy duty
- Prevent or reduce the frequency of behaviors associated with acquisition of STDs/HIV
- Build effective decision-making, problem-solving and communication skills

Modification/Transition Process

- SHIP is demonstrated to MSG school staff
- Focus groups conducted at selected Embassy sites to elicit information to be used in modifying SHIP
- Curriculum changed from four 2-hour session format to three 2-hour sessions
- Introduced use of condom practice
- Curriculum changed further from three 2-hour sessions to one 2-hour session and one 1-hour session

Current Project Status

- Delivery of modified program began in February 1998
- Five classes of MSGs have received the intervention
- Follow-up telephone surveys have begun:
 - Control group completed in January 1999
 - Intervention group scheduled for completion in June 1999
- Comparison of newly modified intervention began in April 1999

Pilot Study of an HIV Prevention Interactive Video in the U.S. Army

Dooley Worth, PhD, Donna Ruscavage, MSW,
LTC Shirley Newcombe, CDR John Mascola

Purpose

To evaluate an HIV prevention interactive video for potential use in the U.S. Army

Objectives

- To determine the feasibility of implementing a brief interactive HIV prevention intervention (interactive video) with selected Army personnel
- To obtain feedback on the appropriateness, content and quality of the interactive video
- To assess attitudes and intention to change behavior regarding HIV prevention

Research Areas

- Previous experience with interactive media for health education and playing interactive videos, computer games and video arcade games
- Experience with HIV prevention interactive video being tested
- Recipient characteristics
- Key informant experiences with HIV prevention and perceptions of HIV prevention needs among military personnel they supervise/work with

Sample

- 29 single, enlisted Army personnel at WRAMC:

Gender: 24 men; 5 women

Age: 18-29; average age = 23

Race: 64% White; 24% African-American;
7% Hispanic; 5% Other

Rank: 62% E4; 17% E3; 14% E5; 7% E2

- 5 key informants

Data Collection Methods

- Individual interviews
- Focus groups
- Participant background questionnaires
- User feedback data
- Key informant interviews

Preliminary Findings

Having to participate in the study on their own time was a major barrier for soldiers:

- While 29 individuals were interviewed or attended focus groups, more than 231 out of the 500 soldiers living in Abrams and Delano Halls played the interactive video
- Among those soldiers who played the video, over half played it more than one time

Preliminary Findings

Playing the interactive video:

- Reinforced already existing intent to protect against HIV infection
- Called into question previous risky behaviors
- Increased awareness of present risk for HIV and behaviors that can put a person at risk for HIV
- Changed present and future intent to protect self and sex partner(s) against HIV infection

Preliminary Findings

The majority of study participants found the interactive video:

- Appropriate not just for use in the Army, but in all the services
- High quality, well-made, innovative and engaging

A Tri-Service Study of HIV Education and Prevention Needs in the U.S. Military (RV 128)

James A. Wells, PhD, Donna Ruscavage, MSW,
CDR John Mascola

Purpose

To document HIV education/prevention needs among HIV educators and recipients of HIV education in the Air Force, Army, Marine Corps and Navy in order to make recommendations for improved training doctrine

Objectives

- To assess previous HIV education/prevention efforts in the services
- To assess current HIV education/prevention needs in the services
- To study information gaps and identify ways to improve HIV education/prevention programs in the services
- To assess attitudes toward HIV education and HIV risk and determine the recipients of HIV education in the services

Research Areas

- Previous HIV education/prevention efforts
- Current HIV education/prevention needs
- Information gaps and ways to improve programs
- Recipient characteristics

Sample

- 1) 4,608 participants = 1,152 recipients of HIV education in each service (Air Force, Army, Navy, Marine Corps) drawn from current DMDC active duty rosters; over sampled women and officers
- 2) 280 active HIV educators all services

Data Collection Methods

- Self-administered mail questionnaire (survey)
- Reminder post cards
- Follow-up questionnaire mailings
- Follow-up telephone interviews

Respondents as of September 1999

- HIV Education Recipients = 3,769

702 Army

1,174 Navy

962 Air Force

931 Marine Corps

- HIV Educators = 135

Pilot Study of a Modified Behavioral Intervention to Reduce HIV/STD Risk Behaviors

David Celentano, PhD, Jonathan Zenilman, MD,
Craig Hendrix, MD, Donna Ruscavage, MSW,
Vivian Go, MPH, CDR John Mascola

Purpose

To assess the feasibility and short-term impact of a modified behavioral intervention to reduce HIV/STD risk behavior and develop plans for a large, multi-site tri-service study

Objectives

- To modify an NIMH behavioral intervention to reduce HIV/STD risk behaviors in the military
- To determine the feasibility of implementing the modified intervention with military personnel in all services, including collecting urine specimens to test for selected STDs
- To plan for a multi-site, tri-service study to test the efficacy of the modified intervention in a randomized, controlled trial with populations at risk

Data Collection

Data will be collected in three areas:

- 1) Participant feedback on the appropriateness, content, format and quality of the NIMH intervention through focus groups with enlisted personnel in all services
- 2) Participant background demographics, attitudes, self-reported behavioral practices and STD/HIV and alcohol/drug history
- 3) Participant point prevalence for selected STDs (chlamydia, gonorrhea, syphilis, herpes)

Two Stage Pilot Study

Stage I:

- 1) Modify the existing NIMH intervention using qualitative methods (focus groups, key informant interviews)
- 2) Identify potential research sites to test modified intervention
- 3) Select research sites
- 4) Develop sampling plan

Two Stage Pilot Study

Stage II:

- 1) Test modified intervention
- 2) Assess impact of modified intervention
on STD/HIV rates

Project LIGHT

- Living in Good Health Together
- Intensive, interactive intervention
- Seven 90 minute sessions
- Designed to create motivation for behavior change, along with individualized skill building to accomplish personal HIV-related goals
- Based on social cognitive theory

Social Cognitive Theory

- Emphasizes skill acquisition
- Asserts that self-efficacy (belief in the ability to engage in required behaviors) influences choice, effort and persistence in effectively using skills
- In Project LIGHT, skill and self-efficacy are achieved by modeling effective behaviors and providing opportunity for graded mastery of skills through practice

HIV Policy and Prevention Materials Under Development for the United Nations Department of Peace-keeping Operations

- 1) Commanders' Briefs
- 2) Field Handbook
- 3) HIV Prevention Modular
Course

Produced with support from the Ford Foundation in collaboration with the Civil-Military Alliance to Combat HIV and AIDS, and assistance of the U.S. Military HIV Research Program and the Henry M. Jackson Foundation for the Advancement of Military Medicine

United Nations Department of Peace-keeping Operations

```
graph TD; A[United Nations Department of Peace-keeping Operations] --> B[Civil-Military Alliance to Combat HIV and AIDS]; B --> C[U.S. Military HIV Research Program]; C --> D[Henry M. Jackson Foundation for the Advancement of Military Medicine]; B --> E[Ford Foundation];
```

Civil-Military Alliance to
Combat HIV and AIDS

Ford
Foundation

U.S. Military HIV
Research Program

Henry M. Jackson Foundation for the
Advancement of Military Medicine

Commander's Briefs

- 1) General Policy Guidelines on HIV
- 2) Policy Guidelines on STD/HIV Prevention Education
- 3) Policy Guidelines on Condom Promotion and Provision
- 4) Policy Guidelines on HIV Testing and Counseling
- 5) Short Course Outline: HIV Prevention and Behavior Change in International Military Populations
- 6) AIDS in the Military: UN AIDS Point of View
- 7) Winning the War Against HIV and AIDS: A Handbook on Planning, Monitoring and Evaluation for HIV Prevention and Care in the Military

Field Handbook: Personal Survival Guide for Peacekeeping Troops

- Personal Data
- Calendars
- Surviving HIV and AIDS
- Peacekeepers Creed
- Peacekeepers Code of Conduct
- Survival Checklist
- Hostage Incident Card
- Hints for Stress Management
- Flags
- Fahrenheit/Celsius Conversion
- Miles/Kilometers Conversion
- Signal Identification
- Maps
- Elements of First Aid
- Time Zones of the World
- Land Mine Awareness
- UN universal precautions
- UN abbreviations
- UN medals

HIV Prevention Modular Course: HIV Prevention and Behavior Change in International Military Populations

- Course Overview
- Module 1: Defining HIV and Its Impact on the Military
- Module 2: HIV Prevention
- Module 3: Substance Abuse, HIV and STDs
- Module 4: HIV Risk Assessment and Prevention Strategies
- Module 5: Course Summary

HIV Prevention and Behavior Change in International Military Populations Curriculum Development Advisors

- **COL Peter Leentjes, UN
Department of Peace-
keeping Operations**
- **Norman Miller, Ph.D.,
Civil-Military Alliance**
- **Stuart Kingma, MD, Civil-
Military Alliance**
- **LTC Craig Hendrix, U.S.
Air Force and Jackson
Foundation**
- **CDR John Mascola, U.S.
Navy and U.S. Military HIV
Research Program**
- **William Lyerly, U.S. Agency
for International
Development**
- **Peter Gordon, UN HIV &
Development Programme**
- **Manual Carballo,
International Center for
Migration and Health**

**Curriculum Developers: Donna Ruscavage, M.S.W. and
Paul Purnell, M.S.**

U.S. Military HIV Research Program

1 Taft Court
Suite 250
Rockville, Maryland 20850
301-251-5000
Fax: 301-294-1898

Fax Cover Sheet

Date: 10/15/99

To: Sandra Thurman

Fax Number: (202) 456-2439

From: Donna Rusavage

Phone Number: 202/456-7959

Subject: Africa Meeting

Total number of pages 5 including this sheet

Comments:

Sandy- Here's the information on the upcoming
military meeting in Pretoria, South Africa

Thanks again for your time today.

Donna

f. u

RESTRICTED

SG(2)/R/522/2

Telephone: (012) 6715202
Fax: (012) 6715186
Enquiries: Maj Y. Kilian

SA Military Health Service
(Section Foreign Relations)
Private Bag X102
Centurion
0046

9 June 1999

**3RD ALL AFRICAN CONGRESS OF ARMED FORCES AND POLICE MEDICAL
SERVICE (AACAFPMS)**

1. Attached please find the 2nd announcement of the abovementioned congress.
2. Kindly forward the announcement to the Medical Corps of your Defence Force.

Kind Regards



PP (MAJOR GENERAL J.L. JANSEN VAN RENSBURG)
SURGEON GENERAL: LIEUTENANT GENERAL

SECOND ANNOUNCEMENT

**3RD ALL AFRICAN CONGRESS OF ARMED FORCES
AND POLICE MEDICAL SERVICES**



**24 - 28 OCTOBER 1999
PRETORIA, SOUTH AFRICA**

DEALING WITH HIV/AIDS IN THE ARMED FORCES

CALL FOR ABSTRACTS

Hosted by



SAM^{HS}_{GD}

**The South African Military Health Service
Die Suid-Afrikaanse Militêre Gesondheidsdiens**

WELCOME TO PRETORIA, SOUTH AFRICA

On behalf of the Surgeon-General of the South African National Defence Force, the organising committee has great pleasure in inviting you to join us at the 3rd All African Congress of Armed Forces and Police Medical Services. This congress, which focuses on Dealing with HIV/AIDS in the Armed Forces, aims to provide you with the opportunity to listen to peer-reviewed research on HIV/AIDS in the Armed Forces and Police Medical Services, and to join in the discussion of management issues relating to HIV/AIDS.

Broad topics that will be covered in the fields of HIV and AIDS will include: epidemiological trends; the impact of HIV/AIDS; management of HIV, AIDS and STDs; the role of allied health services in the management of HIV infection; HIV and operational preparedness and a session on how the armed forces and police medical services can cooperate on issues relating to HIV and AIDS.

The scientific programme will begin each broad topic with a plenary or keynote lecture session by leading experts within the field of HIV/AIDS, followed by symposium sessions selected by a process of peer review, or discussion panels where all delegates can provide input. We invite all participants interested in presenting papers to submit abstracts.

A display area will be set aside for convenient interaction between delegates and commercial exhibitors whose products will be on display during the congress.

In spite of a full and comprehensive scientific programme, we have also allocated time for visits to key military health installations of the South African Military Health Service, as well as more relaxed functions after-hours where delegates can interact and discuss the day's proceedings.

We anticipate that this meeting will provide many opportunities for sharing new experiences and research in the field of HIV by all military delegates.

PRELIMINARY PROGRAMME

Sunday, October 24, 1999

14h00 Registration and Information Desk opens
19h00 Function - Welcoming Cocktail Function

Monday, October 25, 1999

08h30 Opening Ceremony
09h00 Plenary - Historical Background and Epidemiological Trends
10h00 Symposium
10h30 Tea/Coffee Break
11h00 Symposium
13h00 Lunch Break
14h00 Keynote Lectures - The Impact of HIV on Armed Forces
15h00 Panel Discussion
16h00 Function - Traditional South African Braai - SITA

Tuesday, October 26, 1999

08h30 Plenary - HIV/AIDS Management
09h30 Symposium
10h00 Tea/Coffee Break
10h30 Symposium
12h30 Lunch Break
13h30 Symposium
15h00 Visit - 1 Military Hospital
16h30 Function - Cocktail Function - SAMHS Academy

Wednesday, October 27, 1999

08h30 Plenary - Allied Health Services and HIV Management
09h30 Symposium
10h00 Tea/Coffee Break
10h30 Symposium
12h30 Lunch Break
13h30 Plenary - HIV and Operational Preparedness
14h00 Symposium
15h00 Tea/Coffee
15h30 Panel Discussion
19h30 Function - Formal Dinner - Paratus

Thursday, October 28, 1999

08h30 Keynote Lectures - Working Together: The Way Forward
09h30 Panel Discussion

✓ Finalised 29
Civil-Military
Alliance SAKH
Meeting

U.S. Military HIV Research Program

13 Taft Court
Suite 200
Rockville, Maryland 20850
(301) 294-1887
Fax: (301) 762-4177

Fax Cover Sheet

Date: 3 June, 1999
To: Todd Summers
Fax Number: 202-456-2438
From: Deborah Birx
Ext: 1149

Subject: Briefing Information

Total number of pages 4 **including this sheet**

Comments: Enclosed you will find the briefing information you requested. This was prepared by my office and is still being officially reviewed by the command. You should expect to receive an official version from the command, but the substance will be the same. If you prefer an e-mail version, please call Kelley Lennon at ext. 1072 and she can forward it to you.

Thank you.

INFORMATION PAPER

MCMR-PLA

2 June 1999

**SUBJECT: DEPARTMENT OF DEFENSE (U.S. ARMY) HUMAN
IMMUNODEFICIENCY VIRUS RESEARCH PROGRAM****BACKGROUND:**

Human Immunodeficiency Virus (HIV), the virus responsible for AIDS, poses a significant threat to the U.S. Military. HIV infection is epidemic in almost every less well developed and potentially unstable region of the world, and the risk for exposure to HIV by DoD personnel is high. Over 19,000 new infections with HIV occur throughout the world each day. In response to this military-relevant infectious disease threat, a congressionally-mandated research program was begun in 1986 to assess and mitigate the impact on U.S. Military readiness by monitoring the spread of HIV infection in military forces and by developing methods to prevent infection. As lead agent for infectious disease research in DoD, the Army has a highly targeted program to address the military concerns of HIV: Surveillance of infection rates and HIV subtypes around the world; **development of vaccines** and other countermeasures to prevent infection; and clinical studies to avoid immune deficiency. The primary focus of this Program is the prevention of HIV infection in military personnel.

PROGRAM HIGHLIGHTS:

- HIV infection is relevant to today's military. Over 400 new infections occur annually in service members, with a significant number occurring during overseas deployments. This uniformly fatal disease also induces significant acute morbidity, which affects fighting readiness.
- The principal objective of the U.S. Military HIV Research Program is protection and preservation of the fighting force through primary prevention of HIV infection, **ultimately by administration of an effective, preventive vaccine.** *Success in achieving this goal will have broad-reaching application for HIV prevention in civilian populations worldwide.*

Currently, Program efforts focus on:

- 1) education of the force
- 2) surveillance and threat assessment, and
- 3) **a vigorous program of vaccine discovery, development, and evaluation.**

- The Program collaborates with multiple U.S. and international agencies and a network of DoD Overseas Biomedical Research Laboratories to provide an effective surveillance network to monitor the emergence of virological trends in the pandemic and to serve as permanent platforms for evaluation of candidate vaccines in overseas endemic settings.
- The Program has effectively leveraged its vaccine R&D funding and resources to pursue a number of novel candidate vaccine approaches and formulations. Extensive use of Cooperative Research and Development Agreements (CRADAs) with private industry greatly extends the resources of the U.S. Military HIV Research Program.

VACCINE R&D SUMMARY:

The U.S. Military HIV Vaccine Research and Development efforts augment and complement efforts of the DHHS. Domestic clinical trials of candidate vaccines based on the strains of HIV indigenous to the U.S. (genotype B) are conducted to gain familiarity with these novel constructs, to develop an initial safety database to facilitate transition of specific vaccine approaches for evaluation overseas with candidates specifically designed from the HIV viruses which circulate overseas, and, importantly, to harmonize (with the NIH) assays which are critical for evaluating the effects of vaccine candidates on the human immune system.

- Currently, three distinct classes of HIV vaccine candidates (recombinant subunit envelope, canarypox-vectored genes with subunit envelope boost, and facilitated plasmid DNA) are in clinical trials conducted by the U.S. Military HIV Vaccine Program. Clinical evaluation of these constructs is underway in the United States and Thailand. The focus of the Vaccine Development and Evaluation Program in the U.S. and Thailand is to select and then evaluate the most immunogenic of **safe candidate vaccines** for their ability to protect individuals from HIV infection. The current lead candidate is canarypox-vectored HIV (vCP1521) manufactured by Pasteur-Merriex-Connaught, boosted by a recombinant subunit envelope (clade E, manufacturer TBD). Large-scale field efficacy testing is planned to begin in collaboration with the government of Thailand during 2001.
- Pre-clinical R&D of a number of novel candidates is being pursued by the Program, primarily through CRADAs with industry partners. In addition to small animal and macaque studies of novel immunogens (many of which are conducted under the auspices of an NIH contract as a simian vaccine evaluation unit), the U.S. Military HIV Research Program is poised to play a roll in the initial manufacture (by good manufacturing practices – GMP) of several of these new candidate vaccines. This is possible through the Walter Reed Army Institute of Research bioproduction facility at Forest Glen, Maryland. Currently, the Program plans to produce (with corporate partner AlphaVax and the International AIDS Vaccine Initiative) HIV particles based on the Venezuelan Equine Encephalitis replicon platform, and (with corporate partner AVANT Immunotherapeutics) recombinant anthrax antigen-vectored HIV core polypeptides which are called Therapore™HIV.

- Field efforts to prepare for large-scale testing of promising HIV candidate vaccines have been underway in Thailand since 1991. During this period, there has existed an effective alliance with multiple U.S. Government agencies (CDC, NIH, USAID). Efforts in collaboration with the Royal Thai Government have been extensive: national HIV surveillance, development of multiple field sites as potential venues for efficacy testing of promising candidates, creation of a phase I/II AIDS vaccine evaluation network at four academic and government sites, development of extensive in-country laboratory capability and technology transfer to conduct vaccine evaluations, and successful planning, implementation and completion of large multicenter human clinical trials. All vaccine development in Thailand is conducted with candidates incorporating elements of the indigenous Thai HIV (genotype E).
- More recent efforts, beginning last year, have focused on development of a similar field capability in collaboration with government and academic collaborations in Uganda. Vaccine development opportunities in Uganda are unique and complementary to other program efforts. Distinct genotypes of HIV (A and D) co-circulate in this region of the world. The ability to address efficacy and its breadth requires access to sites with such viral diversity. This is a critically important question to be answered in developing vaccines that will be effective for military populations. Again, close coordination with other U.S. Government agencies is envisioned, and will be critical to the success of U.S.-sponsored vaccine development efforts in Uganda.

AVAC "EIGHT YEARS AND COUNTING... WHAT WILL SPEED DEVELOPMENT OF AN AIDS VACCINE?"

In general, we find AVAC's assessments to be accurate. We believe we will be able to conduct a field efficacy trial in Thailand, as stated above. In regards to our pre-clinical activities, we are quite diverse; our resources must be spread in such a way as to avoid excessive risk and optimize our opportunities for development and evaluation of potentially improved future generation candidate vaccines.

A new initiative within the military infectious disease research program and the U.S. Army Medical Research and Materiel Command (of which this Program is one element) calls for annual external peer review – which may meet AVAC's suggestion for increased public input and scientific review.