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Correspondence - Todd Summers - Incoming - 1/99

Stack:	Row:	Section:	Shelf:	Position:
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HIV / AIDS Education Services

"Educating Today For A Healthy Tomorrow"

January 4, 1999

Todd Summers,
Deputy Director
White House Office of National AIDS Policy
736 Jackson Place, NW
Washington, D.C. 20503

Dear Mr. Summers:

I am writing in regard to the National Black Caucus event that took place at the White House on October 28, 1998. Having had the honor of being a part of the President's important announcement, I would like to request a video tape of the entire event.

It was both a rare and a wonderful opportunity that I would like to have a momento of. I will use the tape for my personal memoirs to commemorate my involvement.

If you need any further information from me regarding my request, please contact me.

Thank you for your kind attention to this matter.

Sincerely,

Denise Stokes
PACHA Member

Data Entry Form

Letter ID	Writer First Name	Writer Last Name	Received Date	Subject
11267	Denise	Stokes	1/11/99	

☐ Response Required?

Response Type	Response Date	Responder ID	Responder Name	Action Promised

Action Completed	Action Date	Addressed To
		Todd

Notes

Sender's Organization	Sender's Street1	Sender's Street2
HIV/AIDS Education Services	212 Manor Oak Way	

Sender's City	Sender's State	Sender's Zip
Stockbridge	GA	30281

United States Department of State

Washington, D.C. 20520

BUREAU OF AFRICAN AFFAIRS

Office of Economic Policy
AF/EPS

F A X C O V E R S H E E T

NUMBER PAGES 1 **(including cover sheet)**

DATE: 1/28

TO: Todd Summers

OFFICE: Office National AIDS Policy

PHONE #: _____ **FAX #:** 456-2438

FROM: AF/EPS - Michael G. Heath

PHONE #: (202) 647-3503 **FAX #:** (202) 736-4583

SUBJECT: Todd - The man in the photo is Frank Loy, Undersecretary for Global Affairs

For your clearance

SEEPSA 6565

HIV/AIDS IN AFRICA

In sub-Saharan Africa, 7.4% of all those 15-49 years of age are infected with HIV. This contrasts with 0.5% of adults infected in the United States. Two of every three persons with HIV in the world live in sub-Saharan Africa. Heterosexual transmission accounts for most infections, 50% of which are in women; also over 400,000 infants were infected in 1997 alone.

Early government commitment and intervention can slow the spread of AIDS decisively. While incidence is still high, recent trend data in Uganda show that government efforts can be extremely effective. In 1997, 5-9% of Ugandan adults was infected, compared to 7-12% in 1996. This decrease is most pronounced among the Ugandan youth, concurring with studies which have shown that they are adopting safer sexual behavior (including later sexual initiation, fewer partners and increased condom use).

Nearly all (over 97%) of infected Africans do not know they are infected, mainly because they lack awareness of or access to confidential HIV testing. Young people are at high risk; girls and women more than men due to increased biologic and socioeconomic vulnerability. HIV/AIDS threatens gains made in social and economic development, as well as in life expectancy. Childhood mortality has doubled in Africa. By the year 2010, AIDS will have made orphans of over 40 million children.

The potential political and economic destabilizing effects of HIV/AIDS are profound. Only a small number of individuals with HIV related disease can afford life-saving new drug regimens and moat will die within 5-7 years after becoming infected. Mainly due to the HIV epidemic, African tuberculosis rates have quadrupled -- and the worst in Africa is yet to come.

The USG spends some $60 million annually on HIV/AIDS in Africa (plus CDC medical research). We have focused on prevention of heterosexual transmission of HIV in approximately 30 countries, via programs that: Change risky behavior through education, motivation and innovation; promote condom use; reduce sexually transmitted infections that increase one's risk for HIV; improve the policy environment to reduce the transmission of HIV; conduct research to improve program cost-effectiveness; and increase commitment through advocacy and awareness of individuals' status (voluntary counseling and testing programs). USAID works with key partners, such as multilateral agencies (e.g., UNAIDS), the international and domestic public sector (e.g., Ministries of Health abroad and CDC here), other donors, and the private sector (e.g., local industries, international voluntary organizations).

Cleared: AF/EPS - MHeath
AF/W - PO'Donohue
AID -
P - SSchwartz
D - KDaugherty
S/P - SMorrison
ONAP - TSummers

OFFICE OF NATIONAL AIDS POLICY

EXECUTIVE OFFICE OF THE PRESIDENT

THE WHITE HOUSE

FACSIMILE TRANSMITTAL SHEET

TO: **Paul Delay**	FROM: Todd Summers
COMPANY: USAID	DATE: February 3, 1999
FAX NUMBER: 216-3046	TOTAL NO. OF PAGES INCLUDING COVER:
PHONE NUMBER: 712-0683	
RE: State Dept. document for clearance - UNCLASSIFIED	

☒ URGENT ☒ FOR REVIEW ☒ PLEASE COMMENT ☐ PLEASE REPLY ☐ PLEASE RECYCLE

NOTES/COMMENTS:

Thanks, Paul. I'll call State and tell them that I've asked to put you in the loop.

Todd

736 Jackson Place
Washington, DC 20503
(202) 456-2437
(202) 456-2438 (fax)

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

National Institutes of Health
Bethesda, Maryland 20892

January 13, 1999

Todd Summers
Office of National AIDS Policy
736 Jackson Place, NW
Washington, DC 20503

Dear Mr. Summers:

On behalf of the Joint Satellite Broadcast Workgroup, it is my pleasure to invite you to participate as a member of the studio audience during the satellite broadcast on **Adherence to HIV Therapies: HIV Treatment and Prevention Issues**. This is the third in a series of broadcasts on HIV/AIDS-related topics sponsored by the Department of Health and Human Services.

The 2-hour live broadcast airs on Wednesday, February 24, 1999, from 1:00 to 3:00 p.m. Eastern time. The show is hosted by series moderator, Cindy DiBiasi, and features presentations by Dr. Frederick L. Altice, Yale University AIDS Program; A. Cornelius Baker, National Association of People with AIDS; Dr. John G. Bartlett, Johns Hopkins University, School of Medicine; Drs. Margaret Chesney and Thomas J. Coates, UCSF AIDS Research Institute and Center for AIDS Prevention Studies.

The program will consist of approximately 1 hour of presentations followed by 1 hour of questions and answers, with the questions solicited from the studio and viewing audiences. The studio audience will be comprised of 50 invited Federal and non-Federal guests. The Workgroup is unable to support any travel expenses for this broadcast.

The studio audience is asked to arrive at the FDA broadcast facility in Gaithersburg, Maryland, at least 30 minutes before the broadcast begins and to remain during the entire broadcast. Directions to this facility are enclosed.

Your participation in this exciting event would be greatly appreciated. Please confirm your attendance on the enclosed registration form by February 5, 1999 and fax it to Rose Salton at (301) 468-2245, or confirm by E-mail to rsalton@tech-res.com. If you have any questions, please call me at (301) 443-6364 or send me an E-mail at jkoziol@hrsa.dhhs.gov.

Sincerely,

Juanita Koziol

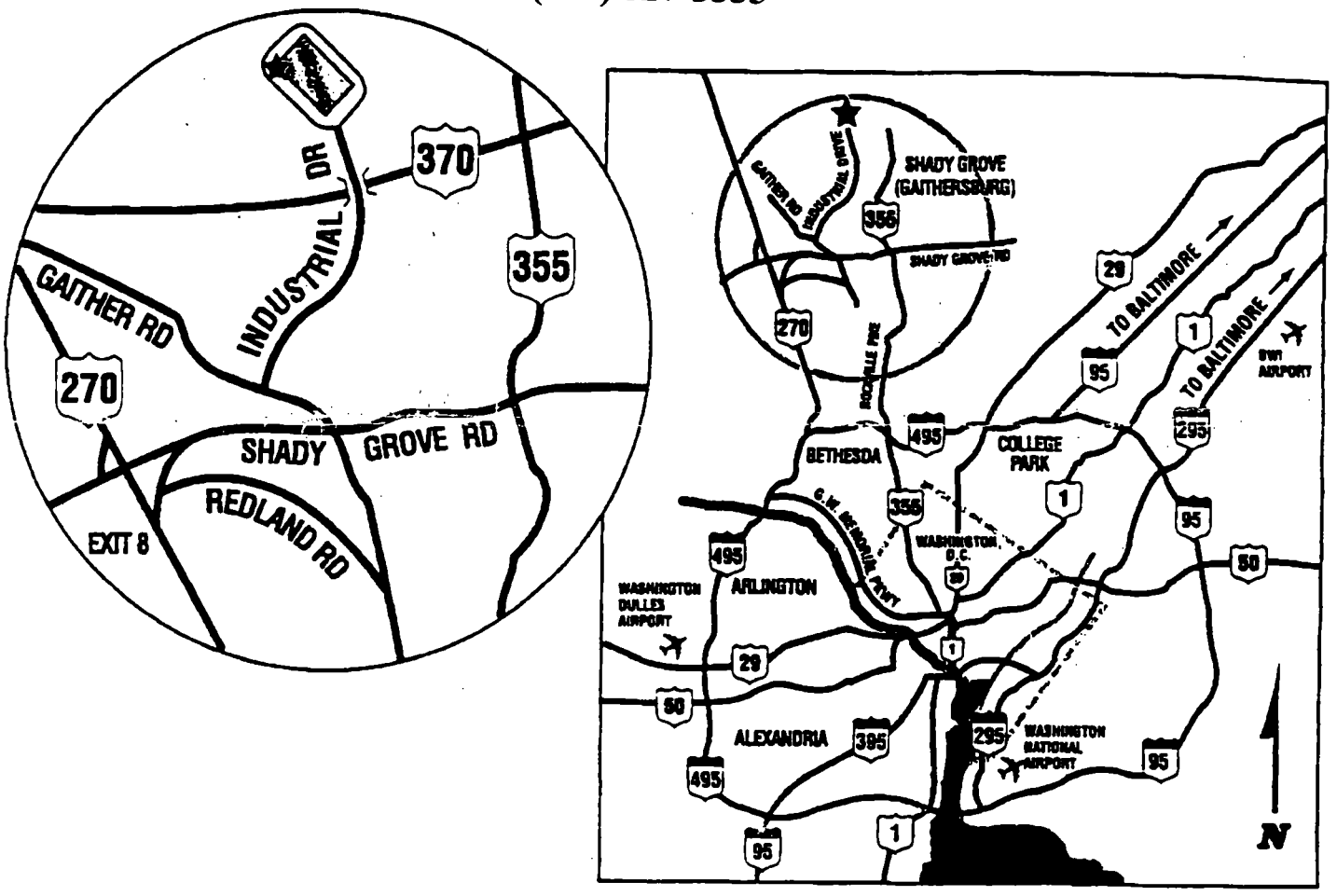
Juanita Koziol, M.S., C.S., R.N.
Chair, Joint Satellite Broadcast Workgroup

Enclosures: Map to FDA Broadcast Studio
Registration Form

CDRH Tech Center

16071 Industrial Drive. Gaithersburg, MD 20877

(301) 827-3555



From the North via I-270: Take I-270 south to Shady Grove Rd. (Exit 8). Turn left (east) at top of ramp onto Shady Grove Road. At third traffic light, turn left onto Gaither Road. Go approximately 0.3 mile to Industrial Drive and turn right. Follow Industrial Drive for approximately 0.5 mile (dead-ends at large white building.) Bear to the left side of the building and drive to the last set of double doors on the right. Enter double doors and check in at guard's desk.

From the South via I-270: Take I-270 north to Shady Grove Road (Exit 8). At end of ramp turn right (east) onto Shady Grove Road. At second light turn left onto Gaither Road. Go approximately 0.3 mile to Industrial Drive and turn right. Follow Industrial Drive for approximately 0.5 mile (dead-ends at large white building.) Bear to the left side of the building and drive to the last set of double doors on the right. Enter double doors and check in at guard's desk.

From Rockville via Route 355: Turn left (west) onto Shady Grove Road. At third light turn right onto Gaither Road. Go approximately 0.3 mile to Industrial Drive and turn right. Follow Industrial Drive for approximately 0.5 mile (dead-ends at large white building.) Bear to the left side of the building and drive to the last set of double doors on the right. Enter double doors and check in at guard's desk.

From Metro: Take the Red Line to the Shady Grove station (last stop on the Red Line). Metro station is approximately 4 miles from Tech Center. Take a taxi to the building (no bus service is available.)

Satellite Broadcast

Adherence to HIV Therapies: HIV Treatment and Prevention Issues

Wednesday, February 24, 1999

1:00 - 3:00 p.m. EST

Registration Form

Please type or print clearly.

Name:	Degree:
Title:	
Department:	Division:
Affiliation:	
Mailing Address:	
City/State/Zip:	
Daytime Phone: ( )	Ext.: FAX Number: ( )
E-mail:	

_____ Yes, I will attend the **Adherence to HIV Therapies: HIV Treatment and Prevention Issues** broadcast

_____ No, I will be unable to attend the broadcast

Please register early as space is limited!

Please return this form by Friday, February 5, 1999, to:

Rose Salton, Conference Coordinator

Technical Resources International, Inc.

3202 Tower Oaks Boulevard

Rockville, MD 20852

Telephone: (301) 770-0610

FAX: (301) 468-2245

E-Mail: rsalton@tech-res.com

GOVERNMENT AND PUBLIC RELATIONS

THE Sheridan GROUP

FAX TRANSMITTAL

DATE: January 5, 1999

TO: Todd Summers

FAX #: (202) 456-2438

FROM: Grayson Fowler

13 *PAGES INCLUDING COVER SHEET*

1808 SWANN STREET NW ▪ WASHINGTON DC 20009
phone 202.462.7288 *fax* 202.483.1964

USSC
U.S. STRATEGIES CORP.

1055 N. Fairfax Street, Suite 201, Alexandria, VA 22314 Phone: (703) 739-7999 Fax: (703) 739-7995

FAX COVER LETTER

December 30, 1998

TO: Tom Sheridan / Grayson Fowler (202-483-1964)

FROM: Gary Capistrant

MESSAGE: Raab memo (you may already have) and Coleman response/rebuttal

Number of pages, including this cover letter: 12

Please contact me immediately if you do not receive all pages transmitted (703-299-5562). Thank you.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Office of the Secretary

The General Counsel
Washington, D.C. 20201

MEMORANDUM

TO : The Secretary

FROM : Harriet S. Rabb

SUBJECT: Skilled Nursing Facility
Prospective Payment System

I have prepared this memorandum for your use in responding to inquiries you have received about a proposal to alter the payment methodology under the prospective payment system (PPS) for Medicare skilled nursing facilities (SNFs). In the Balanced Budget Act of 1997 (BBA), Congress enacted a SNF PPS and prescribed a methodology for calculating payment amounts for SNF services. Under the theory that a separate payment for non-therapy ancillary SNF services is an "adjustment" of the rate for case mix, HCFA has now been asked to reimburse non-therapy ancillaries on a cost basis for an unspecified period of time until certain case mix data are developed.

We have reviewed the relevant law and other materials. We have met with proponents of reimbursing non-therapy ancillaries on a cost basis to understand the rationale supporting their position. Based on our review, we conclude that neither the statute nor its legislative history supports the proposed treatment of non-therapy ancillary service costs.

Section 1888(e) of the Social Security Act, as added by section 4432 of the BBA, specifically prescribes a methodology for determining payments under SNF PPS. The statute sets forth a methodology for calculating facility-specific rates (which reflect a facility's own costs in a 1995 base year) and the federal rate (which reflects average costs). During a transition period, the "amount of the payment for all costs . . . of covered skilled nursing facility services" is "equal to" the sum of two figures: (1) a specified percentage of the applicable facility-specific rate, and (2) a specified percentage of the applicable federal rate. (Emphasis added.) After the transition period, the "amount of the payment for all costs" is "equal to" the

SENT BY:Xerox Telecopier 7021 ; 1- 4-99 ; 1:06 ; 7037397995→ 2024831964;# 2
12/30/98 13:20 ☎ ☑002
DEC-22-1998 16:11 HCFA LEGISLATION 2026908168 P.02/04

DEPARTMENT OF HEALTH & HUMAN SERVICES Office of the Secretary

The General Counsel
Washington, D.C. 20201

MEMORANDUM

TO : The Secretary

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As noted above, under the statute, the SNF prospective payment is for "all costs." The statute specifically defines the term "all costs" to include ancillary costs, but not to include certain other costs. If HCFA were to remove non-therapy ancillary costs from the PPS payment, other costs, or even "all costs," arguably could similarly be removed from the payment calculation. This not only would defeat the concept of "bundling" inherent in the SNF PPS, but also, taken to its logical end, could mean that "all costs" would be reimbursed outside the PPS rate -- a result directly contrary to the statutory requirement for a new SNF reimbursement system. Prospective payments to SNFs are "global" payments that encompass a "bundle" of services. In the BBA Conference Report, "[t]he Conferees note that under the proposed SNF prospective payment system, services and supplies provided to residents will be included in pre-determined per diem payment rates." H.R. Conf. Rep. No. 105-217, at 755 (1997) (emphasis added). Thus, Congress explicitly intended that non-therapy ancillary services, which are included in the statutory definition of covered SNF services, be reimbursed under a prospective daily rate. The proposal to reimburse non-therapy ancillaries retrospectively on a cost basis runs directly counter to this framework.

Certain industry representatives have argued that the Secretary is authorized to adjust the PPS rate for case mix and that a pass-through of non-therapy ancillary service costs could be characterized as such an "adjustment" of the PPS rate. We find this argument without merit. HCFA has included a case mix adjustment through the use of resource utilization groups (RUGs). The proponents of the "adjustment" theory acknowledge that use of RUGs is the primary type of adjustment contemplated by Congress, but argue that, since Congress did not specifically prohibit other types of adjustments, HCFA could deem the cost pass-through to be merely another "adjustment" for case mix. In describing the adjustment authority granted to the Secretary, Congress explained that "[t]he actual per diem rate paid to a SNF would include adjustments for case mix based on a resident classification system established by the Secretary to account for relative resource utilization of different patient types." Id. at 758. Congress clearly contemplated that, even after appropriate adjustment, the resulting rate would be a "per diem" rate. Paying costs on a pass-through basis would require more than a mere modification or adjustment of the elements of the Congressionally-mandated per diem rate. The resulting product would differ fundamentally from what Congress mandated and could not properly be characterized as a "per diem" rate. Therefore, paying non-therapy ancillary costs on a pass-through basis is not within the authority granted to the Secretary to make adjustments for case mix.

The Secretary - Page 3

We further considered whether HCFA possesses any general authority to adjust either the statutorily-mandated rates or resultant payment amounts for non-therapy ancillaries. We find no such authority.

We also note that in order to ensure budget neutrality, an increase in aggregate payments resulting from a pass-through of non-therapy ancillary costs would require a reduction in the unadjusted Federal per diem rates for subsequent fiscal years. This means that payment for costs other than non-therapy ancillaries, e.g., nursing services, would have to be lowered under the pass-through approach. This could have a significant adverse impact on facilities that devote most of their resources to furnishing nursing services and the like. In essence, to be budget neutral, paying more for non-therapy ancillaries requires paying less for other SNF services.

Finally, we note that the statutory scheme seems to incorporate a method for addressing the concerns raised by the industry. As indicated above, for the first several years of SNF PPS, payments to individual SNFs are based, in part, on a facility-specific rate, which reflects the SNF's costs in a 1995 base year (including any exceptions or exemptions). Thus, if a SNF with high non-therapy ancillary costs under SNF PPS also had high costs in its base year, the facility-specific rate would reflect the SNF's high costs. In providing for a transition from a facility-specific to a Federal rate, Congress demonstrated both its awareness of cost differences among SNFs and its preferred method for compensating for those differences. HCFA has no authority to address this issue in another way.

FOX, BENNETT & TURNER
750 17TH STREET, N. W.
SUITE 1100
WASHINGTON, D. C. 20006

TELEPHONE: 202-778-2300
TELECOPIER: 202-778-2330

TERRY S. COLEMAN

MEMORANDUM

DATE: December 29, 1998

RE: Analysis of General Counsel's Opinion on HCFA's Authority Under the Skilled Nursing Facility Prospective Payment System

My memorandum dated September 28, 1998, concluded that the Health Care Financing Administration (HCFA) has the legal authority to reimburse non-therapy ancillaries on a cost basis under the skilled nursing facility (SNF) prospective payment system (PPS). The General Counsel of the Department of Health and Human Services has recently written a memorandum to the Secretary concluding that HCFA lacks such authority. The points relied on in the General Counsel's memorandum, however, appear to reflect a misunderstanding of the proposal that had been advanced or can be dealt with by a modification of the proposal's details. Accordingly, the General Counsel's memorandum does not raise any legal barriers to paying for non-therapy ancillaries on a cost-reimbursement basis for a limited period of time while more accurate data are being collected.

Consistency with Statutory Definition of "All Costs"

The initial point made in the General Counsel's memorandum is that, under the statute, the SNF prospective payment system is for "all costs," which is a term defined in the

statute as including ancillary costs. The memorandum argues that if HCFA were to "remove non-therapy ancillary costs from the PPS payment," then logically all other costs defined as being part of "all costs" could be similarly removed. If that were done, the result would be no change to the SNF reimbursement system in the face of a congressional intent to change the payment method.

There is a twofold response to this argument. First, under my previous analysis, non-therapy ancillary costs would not be removed from the definition of "all costs" that are subject to the SNF PPS payment. Rather, non-therapy ancillary costs would remain within the definition of "all costs" but would be subject -- within the SNF PPS system -- to a case-mix adjustment under section 1888(e)(4)(F) of the Social Security Act in the form of a time-limited cost pass-through. Thus, there is no conflict between the proposed payment method and the statutory definition of "all costs."

Second, my analysis does not lead to the possibility that the SNF prospective payment system could be eviscerated by paying for all costs on a pass-through basis. Since the statutory authority at issue is available only for case-mix adjustments, and HCFA has already determined that significant parts of the payment should not be subject to a case-mix adjustment, there would be no basis to pay for those portions on a cost pass-through basis.[1] In addition, because the RUG system is the basic statutory means for case-mix adjustment, it would be appropriate for HCFA to substitute a different method only if the RUG system is inadequate.

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[1] For urban SNFs, the interim rules establish payment rates of $55.88 for the non-case-mix adjusted portion and $10.91 for the therapy non-case-mix adjusted portion. (The rural amounts are $56.95 and $11.66, respectively.) For many of the RUG categories, this non-case-mix adjusted portion is more than half the total amount, and for others it is a substantial fraction.

While the existing RUG system is inadequate to account for case-related differences in non-therapy ancillary costs, there is no evidence that it is inadequate for other costs and hence no basis to depart from its use. In short, my analysis does not lead logically to an indefensible result, as suggested by the General Counsel's memorandum.

Consistency with Statutory Requirement for a "Per Diem Rate"

The next point in the General Counsel's memorandum is that a case-mix adjustment in the form of a cost pass-through would be inconsistent with the statutory requirement that payments take the form of a "per diem rate." As I previously argued, the term "per diem rate" is not defined in the statute, and it would therefore seem that HCFA has the authority to interpret the term as encompassing rates that include a cost pass-through element. In any event, it would be possible to modify the previous proposal somewhat and design an adjustment that would adequately take case mix into account in paying for non-therapy ancillaries and also take the form of a per diem rate. A revised proposal that meets these criteria is attached to this memorandum.

Under such an approach, benchmark per diem rates for non-therapy ancillaries would be established. The notice published in the Federal Register on November 27, 1998, stated that, for the urban rates, 43.4 percent of the nursing component is associated with non-therapy ancillary costs (42.7 percent in the case of the rural rates). Benchmark per diem rates can be calculated based on these percentages. For cash flow purposes (and because the rates in the PPS payment software cannot be changed in the short term), the rates published in the Federal Register on May 12, 1998, would be used for the initial payments for non-therapy ancillary services. Then, at the time of the tentative final settlement of each SNF's cost report, the

facility's actual per diem costs for non-therapy ancillaries would be compared to the benchmark per diems, and the difference would be paid or recouped as appropriate in the form of an adjusted per diem rate. In other words, each SNF would receive a per diem rate for non-therapy ancillary services that was adjusted to reflect its actual per diem costs for such services. This approach, which could be implemented by interim regulations, would establish cost-related payments for non-therapy ancillaries that are literally and undeniably per diem rates.[2]

Such an approach might be questioned on the ground that, while it would indeed result in per diem rates for non-therapy ancillaries, they would not be prospectively established per diem rates. There is, however, no explicit statutory requirement that the per diem rates be pre-determined in their entirety. The General Counsel's memorandum to the Secretary quotes language from the congressional conference report in which the system is characterized as involving "pre-determined per diem payment rates."[3] Committee report language is, of course, not legally governing. Moreover, the particular language quoted is a poor guide to congressional intent on the issue at hand because it appeared in the context of discussing the need for certain case-mix adjustments, not in the context of describing the nature of the per diem rates. A committee report's off-hand description of a statute should not be interpreted as prohibiting a system that would conform to the actual statutory language and would include an element that would carry out Congress's intent that there be adequate case-mix adjustment. Since the statute

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[2] As noted in my previous memorandum, it is appropriate for the changes to be retroactive to July 1, 1998, because there was no opportunity for public comment prior to issuance of the interim rules, as required by the Administrative Procedure Act and the Medicare statute.

[3] H.R. Conf. Rep. No. 217, 105th Cong., 1st Sess. at 758 (1997).

does not specify that the per diem rates must be prospectively determined, HCFA has the authority to adjust a portion of the per diem rates based on per diem costs actually incurred.

Budget Neutrality

The General Counsel's memorandum also suggested that, to ensure budget neutrality, an increase in aggregate payments resulting from a pass-through of non-therapy ancillary costs would require a reduction in the unadjusted Federal per diem rates for subsequent fiscal years, thus reducing funds available for other types of SNF costs. This is, however, not a legal obstacle.

The General Counsel's memorandum appears to assume that the only method for assuring budget neutrality is the mechanism in section 1886(e)(4)(F) of the Medicare statute by which Federal per diem rates can be adjusted for a future year if the case mix adjuster used in a previous year resulted in aggregate payments that did not reflect actual changes in case mix. There are two other mechanisms that can also be used, however, which do not raise the issue addressed by the General Counsel.

First, section 1886(e)(4)(F) permits a same-year adjustment of the rates in anticipation of aggregate budget effects resulting from a case-mix adjuster[4], in addition to changes based on previous years' payments. Thus, HCFA can adjust the Federal per diem rates

[4] The provision states that if HCFA "estimates that such adjustments for a future year . . . are likely to" result in excessive aggregate expenditures, it can adjust the payments for subsequent years. Thus, HCFA can adjust the rates for an upcoming year based on projections for that year. In the case of FY 1999, the adjustments can be made retroactive to July 1, since interim regulations were issued to implement the rates.

for FY 1999 to address any budget neutrality issue arising from the use of a cost-related case-mix adjuster in that same fiscal year.

Second, nothing in the statute precludes limitations within the design of the case-mix adjuster to assure budget neutrality. Thus, under the attached proposal overpayments would be recouped from SNFs with low non-therapy ancillary service costs to offset the additional payments made to SNFs with high non-therapy ancillary service costs. This action by itself would tend to bring about budget neutrality. Moreover, the proposal contains authority for HCFA to further adjust the payments if necessary to maintain budget neutrality. This was the approach taken in proposed legislation in 1998, which was scored by the Office of Management and Budget as budget neutral and by the Congressional Budget Office with an asterisk indicating an insignificant budgetary effect.

In short, budget neutrality is not a legal issue. The rules for the case-mix adjustment can be designed to assure budget neutrality to whatever degree of confidence, and with respect to whatever categories of costs, that HCFA deems necessary. Moreover, it should be noted that budget neutrality is a relatively minor issue, since, under the proposal, the cost-based adjustment for non-therapy ancillary services would be in effect for only one year while better data are being collected.

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FROM FBT 778-2330 (TUE) 12. 29' 98 18:37/ST. 18:57/NO. 3560452747 P 2

Conclusion

In summary, the issues cited in the General Counsel's memorandum can be successfully dealt with and do not pose legal barriers to a time-limited case-mix adjustment for non-therapy ancillaries that is based on actual costs incurred.

Terry Coleman

REVISED PROPOSAL

HCFA would provide by interim final regulation for a per diem payment amount for non-therapy ancillary service costs that is fully adjusted to reflect the actual costs incurred by each skilled nursing facility (SNF) for such costs.

The initial payment to each SNF would be based on the payment rates published in the Federal Register of May 12, 1998. At the time of the tentative final settlement for each SNF's cost report, the payment would be adjusted as follows:

- A semi-adjusted payment amount for non-therapy ancillaries for each patient day would be calculated based on 43.4 percent of the nursing component for each resource utilization group (RUG) for urban SNFs and 42.7 percent of such component for rural SNFs.

- HCFA will increase the amount payable to a SNF by the amount by which the facility's reasonable per diem costs for non-therapy ancillary services exceeded the semi-adjusted payment amount for such services. HCFA shall decrease the amount payable to a SNF by the amount by which the facility's reasonable per diem costs for non-therapy ancillary services were less than the semi-adjusted payment for such services

Such adjustment shall be implemented for a SNF's cost reporting period beginning between July 1, 1998, and June 30, 1999.

If these adjustments would result in aggregate federal expenditures for a fiscal year that exceed the expenditures that would have been made in the absence of that requirement, HCFA shall reduce the amount of any additional amounts payable under the adjustment process described above as necessary to assure that the requirement does not increase aggregate federal expenditures in any fiscal year.

FAX MESSAGE

U.S. Agency for International Development
HIV-AIDS Division, Office of Health and Nutrition
Global Bureau
Mailing address: G/PHN/HN/HIV-AIDS
3.07--075M, 3rd Flr, RRB
Washington, DC 20523-3700
U.S.A.

To: Sandy Thurman
Todd Summers

Phone: 456 2438
FAX:

cc:

From: Paul R. DeLay, M.D.,
D.T.M.& H. (Lond)
Chief, HIV/AIDS Division

Phone: 202 712 0683
FAX: 202 216 3046

Pages: 17

Date: 1/5/99

Subject: Coordination & Helms letter

Both documents are included

Paul

FAX MESSAGE

U.S. Agency for International Development
HIV-AIDS Division, Office of Health and Nutrition
Global Bureau
Mailing address: G/PHN/HN/HIV-AIDS
3.07--075M, 3rd Flr, RRB
Washington, DC 20523-3700
U.S.A.

To: Ms. Sandy Thurman, ONAP-456 2438
Dr. Ken Bernard, NSC-456 9390
Dr. Neil Nathanson, NIH-301 496 2119
Dr. Helene Gayle, CDC-404 639 8600
Dr. Greg Pappas, DHHS-301 443 4549
Ms. Nancy Carter Foster, DOS-736 7336

From: Paul R. DeLay, M.D.,
D.T.M.& H. (Lond)
Chief, HIV/AIDS Division

Phone: 202 712 0683
FAX: 202 216 3046

Pages: 3

Date: December 24, 1998

cc:

Subject: COORDINATION OF FEDERAL AGENCY RESPONSE TO GLOBAL HIV/AIDS.

USAID's Congressional Reporting Requirements this year included a request to *"report on the status of efforts to coordinate federal global HIV/AIDS activities, particularly research undertaken with the Centers for Disease Control and the NIH."* I have spoken to a number of you about our proposed response which I have provided below. Could you please review this draft text and provide any comments back to me. I hope that this proposed plan would be acceptable to all of the federal agencies involved and would, indeed, provide better fora to exchange information and look for opportunities to collaborate.

The draft response is as follows:

USAID welcomes this request from Congress to propose a more effective process to improve coordination and collaboration among the various federal agencies who participate in the USG response to the global HIV/AIDS pandemic. In particular, we have long recognized the need for greater communication and

linkages between those who are engaged in research and the development of new technologies (e.g. NIH, CDC, FDA, etc.) and those agencies who are involved in providing direct assistance to countries for services to prevent and mitigate the impact of the epidemic (USAID)

In discussions with other Federal Agencies, our combined past experience has led us to the conclusion that the most useful and efficient method to optimize coordination is through the use of discrete thematic working groups, which focus on specific areas of HIV/AIDS research and service delivery. We feel that the Interagency Task Force for the Development of a Vaginal Microbicide could serve as a model for the functioning of these Thematic Working Groups. We have been in communication with the White House Office of National AIDS Policy and they are prepared to convene a meeting in early 1999 of all relevant federal agencies to review this proposal and seek participation of the appropriate staff and agencies. This meeting would be held with facilitation from the Health Attache of the National Security Council and would be charged with identifying the most critical areas for collaboration

From our discussions thus far, there appear to be four areas where collaboration is most urgently needed across multiple federal agencies. These are:

1. Research and delivery issues surrounding therapeutic interventions for HIV infected persons, which are appropriate for low resource settings.

2. Issues surrounding the development and field testing of therapeutic and preventive HIV/AIDS vaccines.

3. Issues surrounding research and service delivery for reduction of mother to child transmission of HIV.

4. Exploring methods to elevate and improve policy dialogue to achieve increased host country government commitment for both research agendas and expanded prevention and mitigation services.

This initial meeting, under the auspices of the White House Office of National AIDS Policy, would serve to review these potential topics, discuss other possible areas for focus, and would then seek to establish the most appropriate chair for each of these thematic groups and the processes which will facilitate their operations. In addition to inviting all relevant federal agencies to this initial meeting, other appropriate participants will be considered, such as representatives from the President's Advisory Commission on HIV/AIDS.

Again, please review this plan and provide any feedback to me by January 8th. We feel that this proposal is flexible, open ended, and provides everyone with sufficient participation in the initial "planning" meeting so that we will develop a process that serves all of our needs and doesn't add any unnecessary burden to our current workloads. Thanks!!!!

The Honorable Senator Jesse Helms
United States Senate
Chairman, Committee on Foreign Relations
Washington,DC 20510-6225

Dear Senator Helms:

Thank you for your letter in which you inquired about the possibility of the U.S. Government providing funding to Nyumbani Orphanage, a Catholic non-profit institution which works in Nairobi. I am familiar with the good work Nyumbani has done over the years in caring for AIDS orphans and in undertaking advocacy on their behalf. Your concern about orphans in Africa is well placed as there will be an estimated 40 million children in Africa who will have lost one or both parents to HIV/AIDS by the year 2010.

I agree with you wholeheartedly that this crisis of children orphaned by HIV/AIDS in Africa is of critical proportions and needs immediate attention. We, too, have observed that many babies, such as the one you mentioned in your letter, test HIV-positive at birth because they carry their HIV-positive mothers' antibodies. Happily, many revert to HIV-negative status at several months of age when the mothers' antibodies wear off. Unfortunately, though, many of their mothers and fathers will die before these children are grown, thus increasing the burden on society and benevolent organizations such as Nyumbani. However, since there is not enough money in the entire USAID budget to provide institutional care for the millions of HIV/AIDS orphans, we are working on other, practical ways to help.

The best way to decrease the numbers of AIDS orphans is, of course, to prevent their parents from contracting HIV. As you know, USAID has undertaken targeted AIDS prevention and education programs in Kenya and many other countries for the past several years. We know that these prevention programs are beginning to

have an impact. In Uganda, for example, data indicate that numbers of people contracting the HIV virus are beginning to decline due, in part, to prevention and counseling programs, many of which are funded by USAID.

Other programs, include helping families care for members who have HIV or AID-related diseases and assisting extended families provide for orphaned children. We also hope to strengthen community-based activities by providing support to a range of respected organizations such as Nyumbani in undertaking networking, advocacy and support to HIV/AIDS prevention and care activities.

I am also happy to report that on December 8, 1998, the USAID/Kenya Mission Director invited to USAID the distinguished Chairman of the Nyumbani Board of Directors, Kenya's former ambassador to the U.S., the Honorable Denis Afande. They discussed the possible collaboration between USAID and Nyumbani, particularly in the context of the community-based care program which Nyumbani has recently begun. They reviewed potential funding sources, including the $10 million orphans' fund proposed by President Clinton, some of which potentially could become available for use in Kenya. They agreed that there is significant scope to work together on activities of mutual interest such as support to help keep orphaned children within the extended family or the community.

USAID/Kenya completed a new HIV/AIDS strategy in July 1998. Father Angelo D'Agostino, the Founder and Medical Director of Nyumbani, participated with over 200 other stakeholders in meetings to discuss new directions for our HIV/AIDS program. As a result of those discussions, a series of new initiatives are underway. These include programs to work with families, communities and institutions to address the needs, including the needs of orphans, which were voiced during the strategy development process. Most of these new initiatives will be in place by April 1999. I hope and fully expect that Nyumbani will be a collaborating partner in undertaking elements of these new initiatives which touch on community-based care for orphans.

In response to the query in your letter, I can state unequivocally that the children in Africa -- including orphans -- are an enormous priority for USAID. We will continue to make every effort to assure their health and well being. We look forward to continuing the dialogue with Nyumbani and the many other deserving community groups and religious organizations in Kenya about how USAID can best respond to their needs.

Thank you and best wishes for the holiday season.

Sincerely,

Brian Atwood

January 25, 1999

Todd A. Summers
Deputy Director
White House Office of National AIDS Policy
736 Jackson Place, N.W.
Washington, D.C. 20503

Dear Mr. Summers:

On behalf of the International AIDS Vaccine Initiative, I write to express my deep concern regarding recent cuts to the AIDS research program at the U.S. Department of Defense and to urge that the administration increase DOD's AIDS research funding by $15 million.

IAVI is dedicated to the swiftest possible production of one or more safe, effective, and accessible preventive HIV vaccines for use throughout the world. In support of this objective, IAVI believes that multiple approaches to vaccine development must be pursued. Late last year, IAVI awarded the two largest AIDS research grants by a nonprofit organization in history, dedicating $9.1 million toward two separate international scientific collaborations to develop vaccines made from African strains of the virus.

DOD's AIDS research program plays a vital role in the search for a safe, effective, and accessible preventive vaccine. More than 50% of DOD's AIDS research budget is devoted to vaccine development. Over the years, DOD's AIDS researchers have undertaken an impressive range of international collaborations.

In years past, Congress routinely increased the amounts for AIDS research proposed in the administration's defense budget. In FY98, for example, Congress increased the President's AIDS research request for DOD by $15 million.

Unfortunately, Congress inexplicably failed to make the usual increased in FY99. As a result, DOD's spending on AIDS research has declined from $35 million to $21 million.

This cut will seriously hamper the search for a preventive vaccine. This loss of funding will force DOD to delay vaccine trials planned in Thailand and Uganda, and it will make it less likely that the country will meet President Clinton's goal of developing a safe and effective vaccine by the year 2007.

IAVI
810 Seventh Avenue • New York, NY 10019-5818 • USA
phone 1-212-655-0201 • fax 1-212-843-0480 • http://www.iavi.org

The global HIV pandemic is spiraling out of control, doubling in size every five years. Each year, six million people, including 600,000 children, are infected with the virus. Now is hardly the time to reduce the U.S. commitment to vaccine research and development.

IAVI strongly urges that the Administration restore DOD's AIDS research program to its prior funding level.

Sincerely,

Seth Berkley, M.D.
President

AIDS VACCINE ADVOCACY COALITION

January 27, 1999

Todd A. Summers
Deputy Director
Office of National AIDS Policy
736 Jackson Place, N.W.
Washington, D.C. 20503

RE: Department of Defense Military HIV Research Program Budget

Dear Mr. Summers:

On behalf of the AIDS Vaccine Advocacy Coalition (AVAC), I write to bring your attention to a recent and severe drop of 40% in the AIDS research program budget at the U.S. Department of Defense in FY1999. If possible, AVAC urges the administration to respond immediately to restore such funding.

Each year in the Armed Services, approximately 400 service members become newly HIV infected, many of these during overseas deployment. Most of these service members are aged 20-29, and a substantial portion are women and African-American. In the armed services, more than 10,000 service members are currently HIV+, approximately 1,200 of whom are on active duty. The Department of Defense established its Military HIV Research Program in 1987 to monitor and prevent new HIV infections, develop better tests and treatments for active-duty personnel stationed throughout the world, and research and develop preventive vaccines to protect U.S. service members in the future.

Since 1987, the U.S. Military HIV Research Program has accomplished a remarkable amount given its limited budget. The Military HIV Research Program was the first to identify the heterosexual transmission of HIV in the U.S., the first to describe global HIV clade variation, the first to develop experimental preventive HIV vaccines against clade E HIV, and the first to develop an international network of research sites to test HIV vaccines.

The DOD's research program for a safe, effective, and accessible preventive vaccine is particularly important for the U.S. and the world. More than 50% of the DOD Military HIV Research Program budget is devoted to vaccine research. This funding is more targeted to product development and testing than NIH funding, and thus has as much or more impact on HIV vaccine development than the NIH effort.

In years past, Congress routinely increased the amounts for AIDS research proposed in the administration's defense budget. In FY1997 and FY1998, Congress increased the President's AIDS research request for DOD by $15 million. Unfortunately, for the FY1999 budget, Congress inexplicably omitted the plus-up at the last minute. As a result, DOD's spending on AIDS research has declined from $35 million to $21 million, with most of this decrease coming from the HIV vaccine effort.

AIDS VACCINE ADVOCACY COALITION

Military HIV Research Program Budget – Page Two

As you know, the DOD did not request additional funding for FY1999 or for FY2000, and the DOD staff remain uniformly silent about this decision and its impact throughout the DOD ranks from the Secretary of Defense on down. AVAC cannot speak to the rationale for the DOD sabotaging its own HIV research effort, but we can speak to the impact of this funding decrease.

This funding decrease of nearly 40% will seriously hamper the search for a preventive HIV vaccine. This loss of funding will force DOD to delay vaccine trials planned in Thailand and Uganda, and it will make it less likely that the country will meet President Clinton's goal of developing a safe and effective vaccine by the year 2007.

AVAC is a national coalition of community advocates dedicated to speeding progress toward a preventive HIV vaccine. We have spoken with the research committee of National Organizations Responding to AIDS (NORA) about this matter, and can assure you that there is concern from many AIDS organizations about this issue.

Given the President's personal interest in preventive HIV vaccine research as a potential legacy of his administration, now is hardly the time to reduce the U.S. commitment to vaccine research and development. AVAC strongly urges that the administration take whatever steps are necessary to restore DOD's AIDS research program to its prior FY1997 and FY1998 funding level.

Sincerely,

Sam Avrett
Executive Director
AIDS Vaccine Advocacy Coalition

AVAC • 1875 CONNECTICUT AVENUE, NW #700 • WASHINGTON, DC • 20009-5741
PHONE: 202-387-5517 • FAX: 202-986-1345

DoD Military HIV Research Program (numbers in US $ millions)

Actual Budget (with 10%-25% war tithe removed)

	1993	1994	1995	1996	1997	1998	1999	2000
HIV Prevention	5.1	3.8	2.8	0.6	3.9	3.2	3.4	3.5
Military Infectious Disease Research Program MIDRP	21.3	23	23.7	19.900	13.400	10.900	11.500	12.100
US Army Medical Material Development Agency USAMDA	20.9	20.3	11.9	7.600	7.300	6.200	6.400	6.600
TOTAL HIV Research without 'plus-up'	**47.3**	**47.1**	**38.4**	**28.1**	**24.6**	**20.3**	**21.3**	**22.2**
Added in Congressional 'plus-up'				**15.0**	**15.0**	**15.0**	**0.0**	**?**

President's Budget Request - Program Objective Memorandum (POM)

	1996	1997	1998	1999	2000
Military Infectious Disease Research Program (MIDRP)					
S-17 61 - Basic	0.877	0.762	0.412	0.457	0.488
873 62- Targetd	2.731	2.643	20.589	14.648	13.176
H29 63 A&B	2.729	17.080	2.563	4.510	5.651
US Army Medical Material Development Agency (USAMDA)					
811 64 - Adv Dev	2.532	2.517	0	3.259	2.543
812 65 - Adv Dev	0.189	0.185	0	0.284	2.243
TOTAL HIV Research in POM	**9.058**	**23.187**	**23.564**	**23.158**	**24.101**
Added in Congressional 'plus-up'	**15.000**	**15.000**	**15.000**	**0.000**	**?**

AIDS VACCINE ADVOCACY COALITION

AVAC MISSION STATEMENT

To speed the development of preventive HIV vaccines by analyzing obstacles to HIV vaccine research and advocating to overcome those obstacles.

- A national voice for policy analysis and advocacy on preventive HIV vaccines since 1995
- A coalition of volunteer advocates with established involvement in research advocacy
- A history of providing an accurate, informed, independent, and honest critique of current HIV vaccine research and development
- Working to speed development of HIV vaccines without taking resources away from basic HIV research, drug development, or other prevention research.

AIDS VACCINE ADVOCACY COALITION

The AVAC Board

Steve Wakefield Chicago, IL President

Steve Wakefield is Executive Director of The Night Ministry in Chicago, and is a member of the natio al NIH AIDS Research Advisory Council (ARAC). Steve is also currently a member of the HIVNET Scientific Steering Committee, and was the national chair of the NIH HIV Network for Prevention Tri ils (HIVNET) volunteer Community Advisory Board from 1995 to 1997.

Bill Snow San Francisco, CA Treasure

Bill Snow is currently a member of the AIDS Vaccine Research Committee and the OAR Advisory Council. An advocate for HIV vaccines since 1990, Bill was instrumental in establishing national an local community advisory boards at the AVEG and HIVNET clinical trial sites throughout the countr and served on the vaccine research sub-panel of the 1994-95 NIH OAR Program Evaluation Commit ee.

David Gold, JD New York, NY Board Secretar

An early AIDS treatment activist in New York, David Gold has been active in HIV vaccine advocacy nce 1992 when he convened a city-wide panel in New York to produce the first community-based paper o HIV vaccine research, titled "Community Perspectives on HIV Vaccine Trials". David was the edito of the Treatment Issues newsletter of the Gay Men's Health Crisis from 1990 to 1995, and is currently t e editor of the IAVI Report, the newsletter of the International AIDS Vaccine Initiative that reaches 10, 000 subscribers in 95 countries. David also worked with AmFAR to produce the first directory of HIV vaccine trials as a supplement to their annual directory of experimental HIV treatments.

Dana Cappiello San Mateo, CA

In 1994, Dana founded the Until There's A Cure Foundation, which has raised more than $3 million for AIDS advocacy and services through the sale of an AIDS bracelet. Dana was instrumental in steeri g Until There's A Cure toward early funding of advocacy for preventive HIV vaccines, including start- p grants to IAVI and AVAC in 1996. Dana has orchestrated AIDS awareness events with many natio al sports teams, and national media campaigns with pro-bono ads in publications such as People, Vogu e, and In Style. Dana currently owns and manages an apparel manufacturing company selling to more than 2,000 stores nationwide.

Luis Santiago New York, NY

Luis Santiago has worked on HIV vaccine advocacy since the early 1990's, first with ACT UP New ork, and more recently with the New York Blood Center HIVNET Community Advisory Board and the Treatment Working Group of the Global Network of People Living with AIDS (GNP+). Luis is a reg ular writer for GMHC's Treatment Issues newsletter on HIV vaccine issues.

Adrian Marinovich New York, NY

Adrian began working on HIV vaccine issues as a volunteer with Project Inform in 1996, focusing h work on vaccine liability and compensation issues, and recently interned at a HIV clinical trial site i Lusaka, Zambia.

Sam Avrett Washington, DC

Sam was previously the Associate Scientific Director of the International AIDS Vaccine Initiative, a d prior to that, the administrator of the New York Blood Center HIVNET vaccine trial site.

United States Department of State

Bureau of Oceans and International Environmental and Scientific Affairs

Washington, D.C. 20520

January 22, 1999

MEMORANDUM

TO: HIV/AIDS Interagency Group

FROM: OES/EID - Nancy Carter-Foster

SUBJECT: The Southern Africa Development Community (SADC) Working Group on Transboundary Issue

I will convene a meeting of the HIV/AIDS working group on Tuesday, January 26, 1999, in room 3524 from 3:00 - 5:00 p.m. to discuss preparations for the US-SADC Forum that will meet in mid-April. HIV/AIDS has been accepted by the Forum Secretariats as the major transboundary issue. USAID has been requested to prepare a concept paper (enclosed)* which will serve as the basis for discussion at Tuesday's meeting.

Please phone clearance information to Denise Goode, (202) 736-7112.

NOTE: CONCEPT PAPER WILL BE PROVIDED AT A LATER DATE.

Pat Jordan	USAID/AFR/SA	647-5007
Alex Ross	USAID/AFR/SA	216-3233
Margaret Dula	USAID/AFR/SD	219-0507
Nedra Overall	State/PRM	663-3094
Karen Jo McIssac	State/DRL	647-9519
Elizabeth Bollman	State/IO	736-7467
Paul Delay	USAID/G/PHN	216-3046
Barbara De Zalduondo	USAID/G/PHN	216-3046
Alan Getson	USAID/G/PHN	216-3046
William H. Lyerly	USAID/G/PHN	216-3373
Roscoe Moore	DHHS/OS/OIRH	301-443-6288
Cecilia Gutierrez	DHHS/OS	690-7172
Eric Goosby	DHHS	690-6584
Margaret Scarlett	DHHS/OS/OHAP	690-6584
Helene Gayle	DHHS/CDC	404-639-8600
Victor Barnes	DHHS/CDC/NCHSTP	404-639-0897
Jack Whitescarver	DHHS/NIH	301-496-2119
Karl Western	DHHS/NIH/NIAID	301-402-3258
Kenneth Bridbord	DHHS/NIH/FIC	301-402-0779
Neal Nathanson	DHHS/NIH	301-496-2119
Paul Gaist	DHHS/NIH	301-496-4843
Robert W. Eisinger	DHHS/NIH/OAR	301-402-8638
Steven Hyman	DHHS/NIH/NIMH	301-443-2578
Donald Pohl	DHHS/FDA	301-443-4555
Stewart Nightingale	DHHS/FDA	301-443-1309
Michelle Limoli	DHHS/FDA	301-443-0235
Kerri-Ann Jones	OSTP	456-6028
Ken Bernard	NSC	456-9390
Jim Kelman	USIA	619-5646
Todd Summers	ONAP	456-2438
Shelley Smith	Peace Corps	692-2601
Lani Havens	Peace Corps	692-2601
Lynn Pahland	DOD	703-681-3658
David Hohman	DHHS	301-443-6288
Bill Hurt	DOC	482-2565

U.S. - SADC FORUM

The United States and the Southern African Development Community (SADC) Secretariat have agreed to create a mechanism, or Forum, to enhance relations between the United States and the members of SADC. The Forum will facilitate discussion and collaboration in several areas, including trade and investment, and on political and cross-border issues. The inaugural meeting of the U.S.-SADC Forum is tentatively scheduled for March 1999.

Background

In 1997, as part of the U.S. Government's desire to intensify relations with southern Africa, Secretary of State Albright initiated the position of Special Representative to the Southern African Development Community (SADC) and proposed launching a regular dialogue with SADC. The SADC Secretariat accepted the appointment of U.S. Ambassador to Botswana Robert Krueger as the Secretary's Special Representative to SADC in May 1998, and responded positively to the concept of a formal dialogue between the United States and the SADC.

Objectives

The United States and the Secretariat envision an annual dialogue that will help build deeper cooperation and engagement between the SADC member states and the United States. The Forum will promote regional integration efforts already underway, and help to reconcile U.S. policy toward the region with the needs of the emerging southern African community of nations. While trade, investment and economic development are expected to be a key focus of the Forum, related issues that affect these areas will also be addressed. These include regional stability, crime, anti-narcotics cooperation, public health, democratization and good governance, environmental issues, transportation, and technology. Political matters of interest will also be discussed at the Forum.

The Forum may also benefit the nations of SADC by:

Encouraging trade and investment liberalization throughout the region;

Improving intra-SADC cooperation on cross-border and global issues such as:

migration
fighting crime, including money-laundering and narcotics trafficking
public health, including combating emerging and infectious diseases
ensuring the protection of human rights, including worker rights
protecting the environment

Enhancing regional security and stability.

AIDS VACCINE ADVOCACY COALITION

January 27, 1999

Todd A. Summers
Deputy Director
Office of National AIDS Policy
736 Jackson Place, N.W.
Washington, D.C. 20503

RE: Department of Defense Military HIV Research Program Budget

Dear Mr. Summers:

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AVAC • 1875 CONNECTICUT AVENUE, NW #700 • WASHINGTON, DC • 20009-5740
PHONE: 202-387-5517 • FAX: 202-986-1345

As you know, the DOD did not request additional funding for FY1999 or for FY2000, and the DOD staff remain uniformly silent about this decision and its impact throughout the DOD ranks from the Secretary of Defense on down. AVAC cannot speak to the rationale for the DOD sabotaging its own HIV research effort, but we can speak to the impact of this funding decrease.

This funding decrease of nearly 40% will seriously hamper the search for a preventive HIV vaccine. This loss of funding will force DOD to delay vaccine trials planned in Thailand and Uganda, and it will make it less likely that the country will meet President Clinton's goal of developing a safe and effective vaccine by the year 2007.

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Given the President's personal interest in preventive HIV vaccine research as a potential legacy of his administration, now is hardly the time to reduce the U.S. commitment to vaccine research and development. AVAC strongly urges that the administration take whatever steps are necessary to restore DOD's AIDS research program to its prior FY1997 and FY1998 funding level.

Sincerely,

Sam Avrett

Sam Avrett
Executive Director
AIDS Vaccine Advocacy Coalition

AVAC • 1875 CONNECTICUT AVENUE, NW #700 • WASHINGTON, DC • 20009-5740
PHONE: 202-387-5517 • FAX: 202-986-1345

DoD Military HIV Research Program (numbers in US $ millions)

Actual Budget (with 10%-25% war tithe removed)

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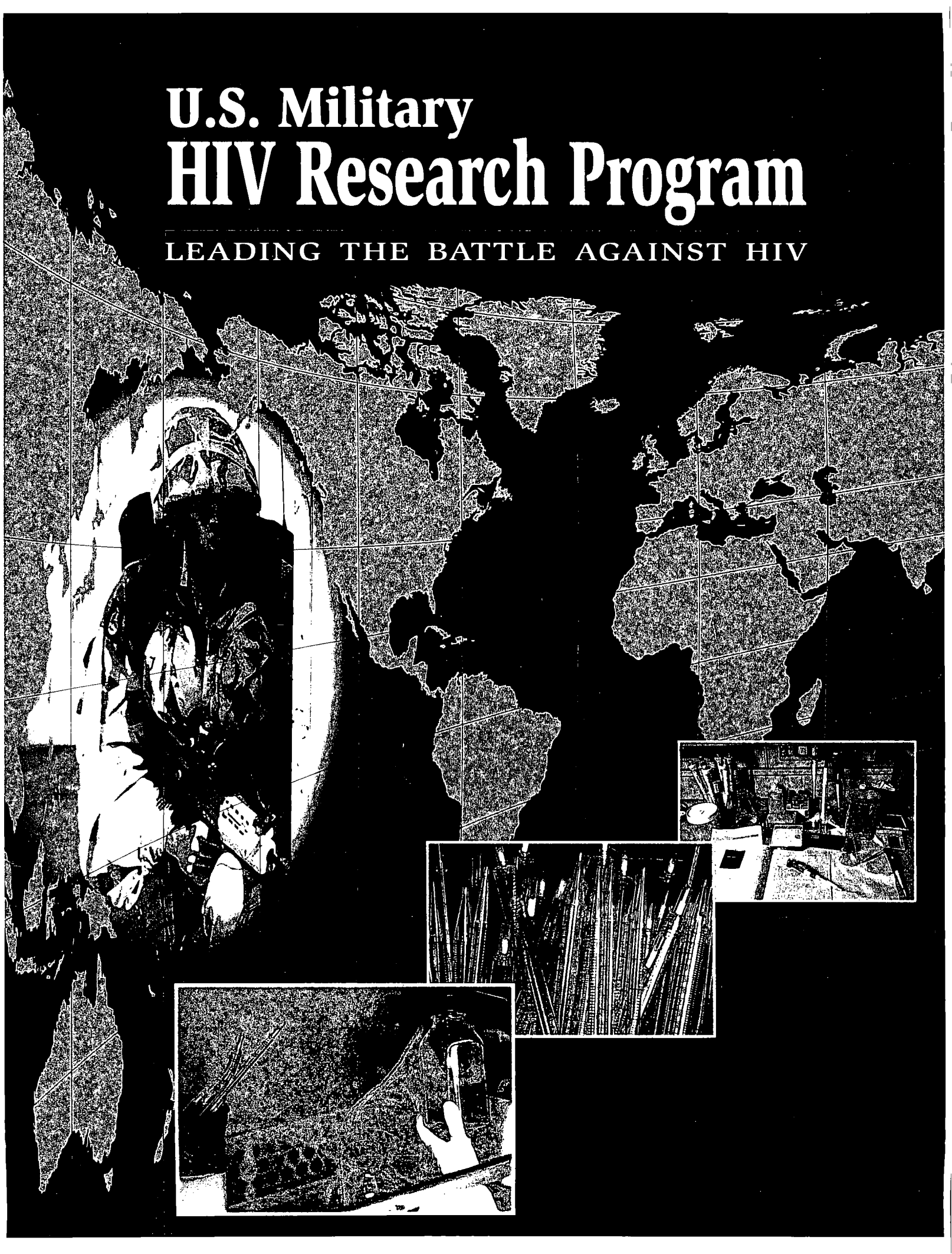
U.S. Military
HIV Research Program

LEADING THE BATTLE AGAINST HIV



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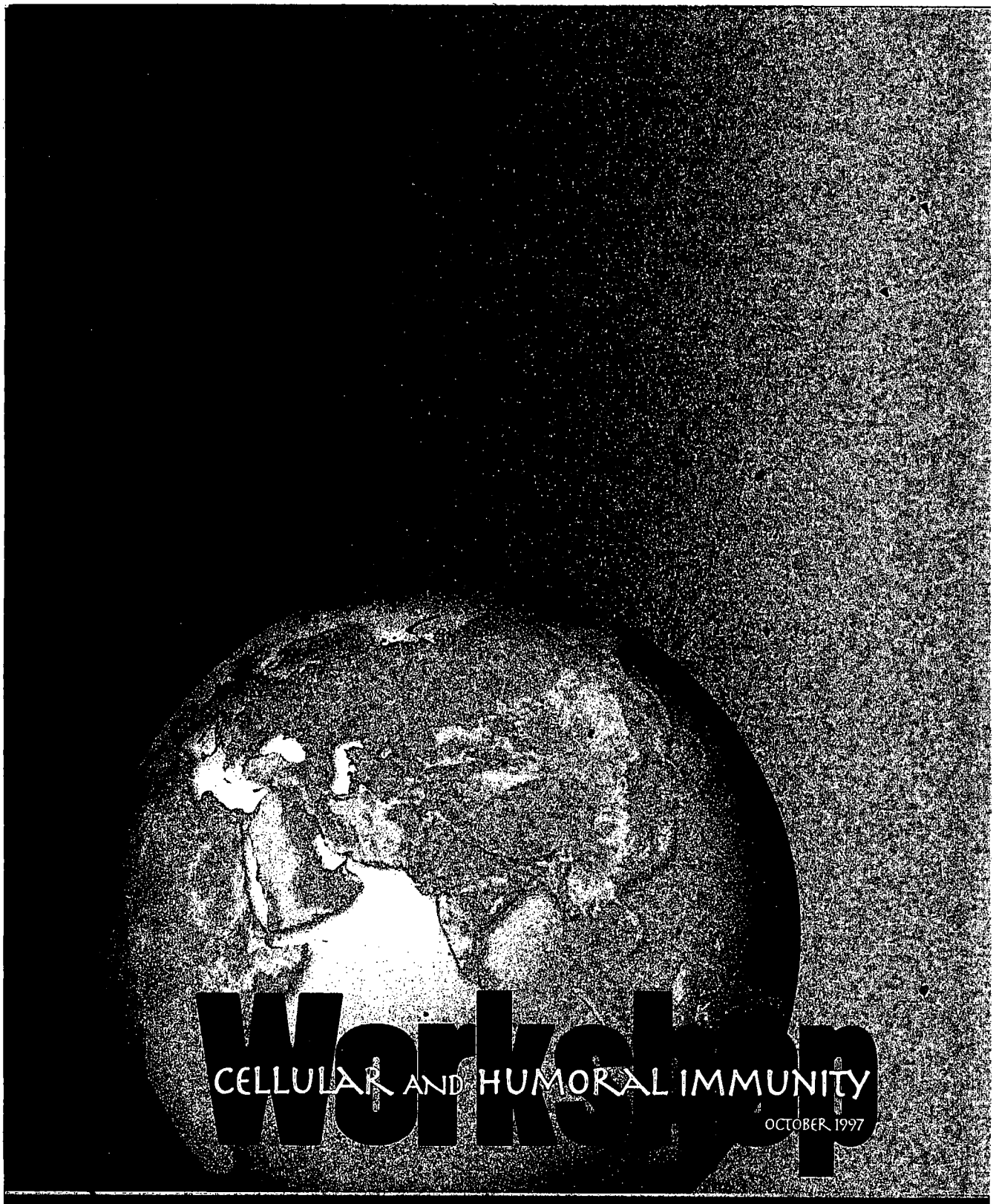
Cellular and Humoral Immunity Workshop
October 1997
Report and Proceedings, Chiang Mai, Thailand



Report on Proceedings

Chiang Mai
Thailand

TO JANE

Human Immunodeficiency Virus Program STEP H

Total HIV Program Funding ($ in M)

FY	Vaccine(%)	Prevention (%)	Clinical (%)	TOTAL Available dollars
93	21.3(45%)	5.1(11%)	20.9(44%)	47.3
94	23.0(49%)	3.8(8%)	20.3(43%)	47.1
95	23.7(62%)	2.8(7%)	11.9(31%)	38.4
96	19.9(71%)	0.6(2%)	7.6(27%)	28.1
97	13.4(54%)	3.9(16%)	7.3(30%)	24.6
98	10.7(54%)	3.2(16%)	6.0(30%)	19.9
99	9.7(54%)	2.9(16%)	5.4(30%)	17.9

(20.106 suppl increase) (15.106 suppl mental) & supplier cuts = 34.9

34.9 + 15.106

15

FY98 Biomedical Technology Area Review and Assessment

Human Immunodeficiency Virus Program STEP H

STEP H Program Attributes:

- Affordability
- Dual-Use
- Commercial Off The Shelf (COTS) Evaluations
- International

16

FY98 Biomedical Technology Area Review and Assessment

HARVARD SCHOOL OF PUBLIC HEALTH
Chairman, Department of Cancer Biology

M. Essex, D.V.M., Ph.D.
Mary Woodard Lasker Professor of Health Sciences

HARVARD AIDS INSTITUTE
Chairman

July 25, 1995

Major General Russ Zajtchuk
Commander
United States Army Medical Research and Material Command
Fort Detrick
Frederick, MD 21701-5012

Dear Major General Zajtchuk:

During the days of May 22-24, 1995 I chaired a committee to review and evaluate the Military HIV/AIDS Research Program. The review committee was composed of eight outside experts representing different areas of AIDS research.

Because of travel and logistical difficulties the report of the committee has still not been finalized. Although it should be finalized soon, I wanted to briefly express the sentiments of the committee before further delay. The review committee was unanimous in the opinion that this research program was excellent and uniquely important in its mission and scope. Although one aspect of the AIDS program, behavior research, was judged to be inadequate, the laboratory research areas were thought to be outstanding.

Of particular note were the areas of international molecular epidemiology and preventive vaccine development. In these particular areas the Military Research Program is the clear worldwide leader in research. This seems important to emphasize because exposure to foreign strains of HIV is of obvious relevance for military personnel, and other US programs, such as the NIH, have fallen behind in this area.

I am hopeful that the final report will be completed very soon, but am still awaiting comments from a few members. If desired, I or other members of the review committee would be available to comment on this report to other appropriate bodies or individuals.

Please do not hesitate to contact me if I can be of further assistance.

Sincerely,

M. Essex

665 Huntington Avenue Boston, Massachusetts 02115 Telephone: (617) 432-1023 Facsimile: (617) 739-8348

EXECUTIVE SUMMARY

The Military Human Immunodeficiency Virus/Acquired Immunodeficiency Syndrome (HIV/AIDS) Research Program represents a multifaceted activity with uniquely important missions and unparalleled opportunities at the national and international level. Apart from obvious considerations of HIV/AIDS morbidity and mortality for any population of young adults, military personnel are at greater risk for exposure to a wider range of HIV strains due to foreign deployments. Therefore, AIDS is and will remain a disease of military relevance. Given the statistics on other sexually-transmitted diseases (STD) among military personnel, protection from HIV through vaccination should be a major priority for the Department of Defense (DoD) military leadership. In addition, regular HIV testing, clinical monitoring and behavioral interventions are areas for the military to maintain. These approaches help provide answers to questions concerning the natural history of HIV disease in an unique population.

The military has several unique capabilities that can impact on the fight against this disease. The development of vaccines to prevent HIV infection is a national and international priority that is relevant to the DoD's mission because of the global exposure of military personnel. The U.S. Army is one of the preeminent developers of vaccines in the world which would logically require the military program to be one of the leaders in the effort to develop an HIV vaccine.

The Military Medical Consortium for Applied Retroviral Research (MMCARR) is the Tri-Service umbrella organization that coordinates HIV research within the military and with other national and civilian efforts. Considerable collaboration exists between the military research focus groups, and with academic and corporate researchers outside the DoD to complement strengths, and to provide important reference viruses and expertise to the national AIDS research effort. These collaborations represent major strengths in the program. Furthermore, the military's reference research facilities in Asia and Africa constitute a close to irreplaceable foreign resource for cooperative vaccine testing.

The five current major research program areas, Global Molecular Epidemiology, Behavioral Prevention, Vaccine Development, Disease Prevention, and Disease Assessment, are logical and well-defined focus areas for emphasis. Several other previous major research programs have been reduced, eliminated, or folded into the five current major research focus areas. This re-orientation and restriction has been at least partly in response to previous recommendations, and builds on the unique needs and capabilities of the DoD and the competence of several of the outstanding researchers.

The Global Molecular Epidemiology Program (GMEP) is an uniquely important national resource to identify and access new HIV strains and to determine the relative prevalence and incidence of such strains worldwide because of its overseas research facilities. The GMEP, one of the most productive groups in the MMCARR HIV/AIDS program, is responsible for the majority of information on strains that originated outside the U.S. These strains are typically associated with different epidemic patterns of transmission (i.e., heterosexual versus other forms of transmission). The GMEP represents an essential window for surveillance information concerning exposure of U.S. citizens to new and emerging HIVs worldwide.

The Behavioral Prevention Program objective is to develop and evaluate behavioral interventions for the three services that will reduce exposure to HIV as well as other sexually-transmitted diseases. This program is indispensable to the protection of DoD personnel from HIV and other sexually-acquired infections, especially in the absence of protective vaccines and increasing antibiotic resistant bacteria. Furthermore, behavioral factors are critical and integral to effective vaccine trials and evaluation. HIV infection is the result of personal risk behaviors

and the lack of personal protection, which can be reduced by educational programs. The Behavioral Prevention Program, however, appears to suffer from a lack of high level behavioral science expertise and clear commitment. As such, critical opportunities for integration of behavioral research with other facets of the military HIV research effort have not been maximized. This program needs to be strengthened, as it is presently the only program that can have a near-term impact on HIV infection rates for the military.

The Vaccine Therapy Program will be phased out at end of the current clinical trials. The committee concurs with this decision, but strongly recommends that the program be funded until after all data have been collected and analyzed.

The objectives of the HIV Vaccine Development Program are to develop and evaluate preventive vaccine candidates against HIVs. The Military HIV Program has outlined a rational, well-defined program of sequential vaccine development and efficacy evaluations to be carried out in partnership with vaccine manufacturers and Thai collaborators. The epidemiologic background work, tracking the growth of the HIV epidemic in Thailand, makes this particular epidemic one of the best studied in the world. The information will be invaluable in planning successful vaccine trials. The group is to be highly commended for its global approach to vaccine evaluation, which has included obtaining required background information, supplying needed cloned viral genes for production of recombinant vaccines, and actively encouraging manufacturers to evaluate their vaccine designs in Thailand, a setting which should allow rapid and efficient clinical trials. The strong working relationship between the Thais and the U.S. Armed Forces Research Institute of Medicine is an important key to this collaboration

The Disease Prevention and Disease Assessment Programs, while potentially overlapping with civilian AIDS research programs, provide an important knowledge-base for vaccine development. The Disease Prevention Program's objectives are to conduct clinical trials of chemotherapy and gene therapy agents. This group has made significant contributions to understanding the crucial roles of drug resistance in disease progression and in prevention of early disease progression under its current leadership. Early interventions are crucial components to maintaining a strong, healthy, military force. The Disease Assessment Program is a critical component of the DoD HIV Program effort dedicated to the study of disease incidence, disease transmission, and disease prevention. This program is responsible for the domestic Natural History Repositories as well as potential vaccine testing populations to derive the clinical, virologic and immunologic correlates of HIV disease incidence, transmission and progression, the assessment of the clinical and field trials and animal model testing of vaccines for prevention, and supports the efforts in practical assay technology development. The Natural History Repositories are one of the major strengths of the DoD HIV effort. This program provides for the collection and storage of primary and longitudinal clinical specimens and data from HIV infected persons throughout DoD facilities and represents a one-of-a-kind collection, the loss of which would be a national tragedy. These repositories constitute the central resource for the surveillance of HIV disease in military populations, providing the DoD and the medical research communities with unique opportunities for understanding critical facets of the epidemic. The Disease Assessment group has assembled and maintained this critical database which can now supply a wealth of information regarding the natural history of HIV.

Important capabilities of the Military HIV Program

- Leader in vaccine development and clinical evaluations world-wide.
- Modern research facilities positioned internationally provide a global surveillance system to study the global HIV threat.

- Strong international ties to potential vaccine trial sites, especially Thailand where two successful efficacy trials have been conducted.
- Developed and maintains the HIV National History Repositories whose collection represents a unique wealth of data important in understanding and studying the HIV virus.
- Provides substantial research support to several national and international HIV research efforts.
- Program has many excellent scientists in several program areas.

Major recommendations:

- Support fully the clinical site preparatory activities in Thailand as they are the centerpiece of DoD's vaccine activities.
- Continue the systematic, rational approach to evaluation of vaccine candidates.
- Organize and network with other international agencies interested in future vaccine efficacy trials in Thailand to minimize redundancy in target populations, and choice of antigens.
- Continue the global viral epidemiological surveillance with an emphasis on alternative potential vaccine sites.
- Maintain the Natural History Repositories as a national resource, and develop broader collaborations with other laboratories to promote the greatest utilization of the repositories.
- Increase surveillance of military personnel returning from overseas assignment. This is clearly within the mission of the DoD HIV effort and will provide a unique forum to study the current HIV epidemic as opposed to clinical cases that reflect past conditions.
- Strengthen research efforts by having greater epidemiologic and statistical input into the design and analysis of studies.
- Continue the support to monitor efficacy of interventional therapies in preventing disease and in treating patients with early HIV disease.
- Enlist the help of nationally recognized behavioral science experts specifically to review the Behavioral Prevention Program. This program needs strengthening and direction. Because of its potential importance to DoD, it should be carefully evaluated by experts before possible elimination or downsizing.
- Increase interdisciplinary nature of research especially behavioral variables, to provide appropriate context for interpretation of study results.
- Integrate HIV research with research on other STDs, many STDs clearly increase the risk for HIV infection, are prevalent in military personnel and are underemphasized, especially in the Behavioral Prevention Program.

More specific comments and recommendations are included in the report.

Reaching Beyond the Science

At the heart of this program is its staff of dedicated and motivated personnel. The commitment of each individual to the search for effective prevention of HIV is immediately evident in the work. The sustained high caliber of science which characterizes this program is testimony to the tireless yet focused efforts of our scientists, technicians, and research support personnel.

Reaching beyond the science, their concern and commitment extends well past the laboratories and into the community. Our staff actively participates in the annual AIDS walk, AIDS rides, serves on community health forums and volunteers in AIDS clinics, and organizes a yearly gift-giving program bringing holiday cheer to hundreds of children touched by AIDS.

Each day our personnel stand together, united, across the country and around the globe, giving of their time and energies both in and beyond the laboratories to combat this devastating disease.

Research "Firsts"

U.S. Military HIV Research Program

- First nation-wide data on HIV
- First program for early diagnosis and treatment
- First HIV staging system (Walter Reed System)
- First identification of heterosexual transmission in the U.S.
- First description of world-wide viral genetic diversity
- First to document dual infection (B and E strains)
- First serotyping system
- First development of vaccines against clade E strain
- First functioning international vaccine testing network

This brochure was produced by the Henry M. Jackson Foundation for the Advancement of Military Medicine and is not an official publication of the USAMRMC. The positions presented herein do not necessarily reflect those of the U.S. Army, the Department of Defense, or the United States Government.

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A Platform for Research Success

A multi-disciplinary scientific team and a responsive research infrastructure in the United States and in overseas laboratories provide the platform for research success.

Strategic Partnerships

At the core of the program is a cooperative agreement with the Henry M. Jackson Foundation for the Advancement of Military Medicine (Foundation). Through the provision of world-class scientific personnel and comprehensive research management and support, the Foundation works side by side with the Military to augment the Program's infrastructure, enhancing research capabilities and furnishing a responsive and flexible research team to facilitate the mission and priorities of this Program.

Strategic partnerships with other government agencies, private industry, and academia also leverage the Program's resources, and further maximize scientific output. With such an integrated, product oriented approach, this Program is ensuring rapid scientific progress and ultimately successful vaccine development efforts. Indicative of its scientific productivity, significant scientific contributions to the current body of knowledge about HIV have been associated with this program. Military and Foundation scientists were ranked as top cited authors in HIV/AIDS research, by Science Watch, and the Foundation was recognized as one of the top ten (#4) HIV/AIDS publishing institutions in the world for 1993-95.

Responsive Research Infrastructure

Through the years, this Program has built a comprehensive infrastructure to meet the needs of the science. A state-of-the-art computer and communications network provides the critical backbone for research data collection, management, and analysis. The network manages and integrates multiple studies and trials at numerous sites in a secure environment which is responsive to researchers' needs. A local area network has been installed in Thailand to support research efforts and is linked to the main network via the internet and electronic mail. A Data Coordinating and Analysis Center at the Rockville laboratory offers researchers, around the world, a comprehensive "concept to product" approach through the provision of unique data management systems and biostatistical support. A Clinical Regulatory Compliance group provides expert national and international trial monitoring capabilities and assists Principal Investigators in protocol development, technical writing, and ensures adherence to regulatory guidelines.

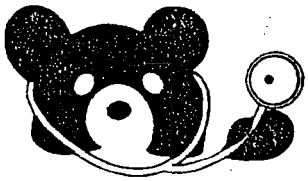
A responsive project management team provides complete research management capabilities including general and laboratory administration, global logistical support and protospecific support which can be tailored to meet site-specific requirements.

Since Thailand was chosen as the first vaccine testing site outside of the United States, it has expanded to provide a solid infrastructure to support the U.S. Military's HIV vaccine development efforts. It includes a fully functional laboratory facility with biosafety level 2 areas, an established presence at multiple medical centers, and active international research sites in Bangkok and Chiang Mai.

A Decade of Research Productivity

Characterized by over a decade of research excellence, this Program has set a gold standard for product-oriented, efficient, and collaborative research. Quantifiable measures of research productivity have included:

- Completion of over 65,000 research protocol visits
- Publication of over 300 original articles in peer reviewed journals
- Foundation ranked as one of the top publishing institutions in HIV/AIDS research
- Completion of 34 human use protocols and a multitude of laboratory projects
- Lowest patient missed visit and drop-out rates for clinical studies compared to all other U.S. AIDS clinical research institutions



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FAX SHEETS No: 4

Todd — Dr. Khan is confident that he will meet w/ Sandy. But I thought maybe you can meet w/ him instead. Stick in intern box tomorrow after you decide. Dr. Khan's been paging me constantly to get an answer. SA

*Date: January 14, 1999

*To: Sandy Thurman - Director

*Firm: AIDS program at the White House

*Tel#: (202) 456-2437

*Fax#: (202) 456-~~3439~~ 2438

*From: Dr. Waheed N. Khan - Director
Microbiology Research in Infectious Diseases
Tel:(202) 884-5546 Fax:(202) 884-5989

Subject: AID'S preventive Test.

Dear Ms. Thurman:

Your secretory Sarah Holinski with whom I had number of conversations to schedule a meeting with you. She suggested that I send this request in writing along with my resume.

I have developed a rapid AID's test which can be used for preventive purposes. Use of condoms have not prevented this dreadful disease to any extant. This test is simple, accurate and inexpensive. This test is good for "Home use".

I would like to meet you for the above mentioned reason and seek your advice for distribution of this useful test. I hope you would find some time for me.

Thanks in anticipation. With best regards.

Sincerely,

Waheed N Khan

Dr. Waheed N. Khan
Infectious Disease Research

Infectious Disease Dept. in Dominican Republic

Developed a collaborative infectious disease research and self-help program at a children's hospital in Santo Domingo, D.R. since 1981. The standard of expertise at the local institution was elevated by sharing knowledge, newer techniques and most modern methods of management. Supported all aspects of clinical work with funds from the pharmaceutical industry. During this gradual development and eventually so much expertise was gained by the local doctors and para-medical people that they became experts at par with the scientists in U.S.A.

Development of New Technology

Developed new technology for rapid diagnosis in infectious diseases. A 15 minute diagnostic test for meningitis, very simple quick, accurate and economical. This new technology was patented (Patent # 4, 067,776,1978).

Detection of Endotoxins in seriously ill patients, i.e., toxic shock and mingocoxcernia.

Rapid test for cancer sensitivity; produces results in 4 hours as opposed to 6 weeks by conventional methods.

New Vaccines

Participated in the development and trials of antimeningococcal vaccine (Group A+C) with Walter Reed Army Medical Research Institute in the early 1970s and lately with Group B meningococcal vaccine trials with the same institute conducting trials in South America.

New pertussis vaccine investigational trials in the Dominican Republic under FDA guidelines and with local physician participation. Worked within Infectious Diseases, i.e., meningitis, pneumonia, otitis media and others. Set up an Infectious Diseases laboratory at a Children's Hospital in Santo Domingo, Dominican Republic which is now at par with laboratories in U.S.A.

Industrial Joint Ventures in China

At Zhangjiang, China, I set up at China joint venture for industrial production of Horseshoe crab blood extract. A very precious and most useful chemical used in pharmaceutical industry for quality control (price, $50/cc). Developed and made Chinese aware of their natural resources. Developed (presently under construction) the full plans for the building of a factory and marketing the chemical, for world wide distribution.

CURRICULUM VITAE

Waheed N. Khan, Ph.D.
Director, Microbiology Research
Children's National Medical Center
111 Michigan Avenue, N.W.
Washington, D.C. 20010
Telephone: (202) 884-5546

EDUCATION

B.S. 1957 University of Punjab, Forman Christian College, Lahore, Pakistan. Biology Major.

M.S. 1963 Howard University, Washington, D.C. Microbiology Major.

Ph.D. 1974 University of Amsterdam, Holland. Clinical Microbiology Major.

CITIZENSHIP

United States

EXPERIENCE

Teaching at University Level

Biology Instructor, Howard University, Washington, D.C., 1959-60.

Microbiology Instructor/Research Assistant, Yale University, New Haven CT, 1960-61.

Microbiology Instructor, George Washington University, Washington, D.C., 1962-63.

Advisor to post-graduate medical students for Ph.D. at Uniform Services University, Bethesda, MD, 1985-present.

Pharmaceutical Industry

Pharmaceutical Bacteriologist and Quality Control Supervisor, Bio-Rama Drug Co., Baltimore, MD, 1961-63.

Industrial Supervisor of Human Tissue Culture; Microbiological Associates, Bethesda, MD, 1963-64. Coordinator and Developer of pharmaceutical products evaluation. Project manager and developer of investigational antibiotics in pediatric age groups. Managed projects under FDA supervision and inspection in Infectious Diseases and on products from pharmaceutical houses, such as Abbot, UpJohn, E.I. Lily, Pfizer, Glaxo, Hoffman La Roche, Merke, Sharp and Dhome, Lederle, Bristol Myers and many more.

Advisor to Health Ministry of Pakistan

During the last administration (President Zia ul Haq's term) I was advisor to the health ministry of Pakistan. I helped in the building of a new medical complex including Children's Hospital of Islamabad. Developed mission statements, goals and objectives, administrative policies and procedures for the hospital and their preventive health program.

FACULTY APPOINTMENT

Adjunct Associate Professor of Preventive Medicine, Department of Preventive Medicine. Uniformed Services University of the Health Sciences, Bethesda, MD, since 1986.

PROFESSIONAL SOCIETIES