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Dear Sandy—

28 April 1997

Congratulations on your selection as the President's new AIDS "star"! I read the glowing report in the Post last week & almost choked on my breakfast — I didn't realize I had been working w/ a ~~second~~ star at the PIC! From your humble "beginnings" as director of Will Call you've achieved great things!

As for me, I'm gainfully employed as a political appointee at the Defense Dept & loving it. Good luck & congrats again... Sincerely, Matt



Matthew N. Gobush

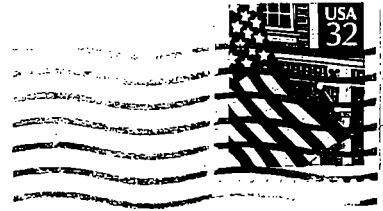
Special Assistant to the Deputy Under Secretary of Defense
International and Commercial Programs

The Pentagon - Room 2B329
Washington, DC 20301

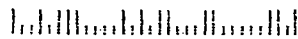
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CLINTON LIBRARY PHOTOCOPY



Ms. Sandy Thurman
Director, AIDS Policy
The White House
1600 Pennsylvania Avenue, NW
Washington, DC 20500



Mott Gabbash
950-25th St., NW
#611 So.
Washington, DC
20037

1

Office of
National AIDS Policy

Correspondence Routing Slip

Tracking Number: G-3649

Date Rcvd: 04-18-97

From: Mario Solis-Marich

Nat'l Task Force on AIDS Prevention

Staff Action:

Reviewed By Sandy: _____ Reviewed By: _____

Assigned To: _____

RCVD: _____ DONE: _____

*She already
with him
Tadd
5/3*

Recommendations/Instructions:

Tom later
JP

To Support Staff: _____

Date of Response: _____



NATIONAL TASK FORCE ON AIDS PREVENTION

973 Market Street, Suite 600 • San Francisco • California • 94103
415/356-8100 • fax 415/356-8103 • e-mail: ntfap@aol.com

April 8, 1997

Ms. Sandy Thurman, Director
Office of National AIDS Policy
750 17th Street, NW, Suite 600
Washington, D.C. 20503

Dear Ms. Thurman:

I am writing to congratulate you on your appointment as Director of National AIDS Policy. We, at the National Task Force on AIDS Prevention, are encouraged by your commitment to improve the lives of all Americans who are living with HIV and AIDS. We wish you great success.

Secondly, I am writing to request a meeting with you. I intend to be in Washington, D.C. in the last week of April and I hope to meet with you at that time. I have instructed my assistant, Kenneth Harper, to contact your office this week in order to schedule an appointment. Please do not hesitate to contact me, anytime, at (415) 356-8123.

Once again, congratulations, I hope that we work together effectively for the health of all Americans.

Sincerely Yours,

A handwritten signature in black ink, appearing to read "M. Solis-Marich", with a long, sweeping horizontal stroke extending to the right.

Mario Solis-Marich
Chief Executive Officer

Office of
National AIDS Policy

Correspondence Routing Slip

Tracking Number: G3656

Date Rcvd: 04-12-97

From: Jessica Pomerantz

Cresskill Jr / Sr High School

Staff Action:

Reviewed By Sandy: _____ Reviewed By: _____

Assigned To: _____

RCVD: _____ DONE: _____

Recommendations/Instructions:

Ann Ed. Wheel
HS level

To Support Staff: _____

Date of Response: _____

Cresskill Jr/Sr High School

1 LINCOLN DRIVE
CRESSKILL, NEW JERSEY 07626

HENRY P. McNALLY
PRINCIPAL
567-5480

PAUL DIVERIO
ASSISTANT PRINCIPAL
567-5481

April 9, 1997

Ms. Sandy Thurman
Aids Policy Director
The White House
1600 Pennsylvania Avenue
Washington, D.C.

Dear Ms. Thurman,

It was with great excitement that I read about your recent appointment as Director of Aids Policy in the Clinton Administration. I was particularly pleased to read that "she tells it like it is. She speaks the truth unvarnished."

I am a junior at Cresskill High School in Cresskill, New Jersey. Variations of the attached letter were sent to President Clinton both this year and last year. While I was pleased to receive a copy of the World Aids Day declaration, I do not see the relation of this document to the topic of Aids Education. I recently sent a letter to Erskine Bowles requesting that he intervene with the President. Unbelievably I receive a reply that thanked me for approving of the president's Aids initiative. This reply gave me the sense that my letter was not given serious attention.

This is the second year that Governor Whitman has taken up my cause by proclaiming the week of May 26 to June 1 Aids Education Week in the State of New Jersey. The second annual Aids Walk will take place on Sunday, June 1. All monies raised will go to the Aids Outreach Fund at Hackensack Hospital. This hospital is a major Aids care giver for northern New Jersey. I am pleased to say that six Bergen County High Schools have already decided to participate in the Aids Walk.

We need the President, Vice President or a cabinet member to join us for this important event. Their presence will send a message to the youth of America that the administration cares about their future. It is imperative that young people stand up and be counted. We must take responsibility for our actions. Aids Education Week in New Jersey has and will continue to have positive effects on the attitudes and lifestyles of many of my peers. Imagine what effect a national Aids Education Week would have?

I realize that my future must be connected to helping make other peoples lives better. This project is my first step. I need your help now! I would also like to be considered for appointment to the Presidents Aids Advisory Panel. My generation must be represented on this panel.

I thank you for your consideration and look forward to your reply.

Sincerely,



Jessica Pomerantz

July 24, 1996

President Bill Clinton
The White House
1600 Pennsylvania Avenue
Washington, D.C.

Dear President Clinton:

I have just completed my sophomore year at Cresskill High School in Cresskill, New Jersey. The highlight of my year was the successful completion of the first annual **Aids Education Week** in the State of New Jersey.

Student responsibility and the Aids virus continue to be of particular concern to me. Cresskill's student population is primarily white and Asian. Many of my peers believe that they are not vulnerable to the Aids virus. This attitude convinced me to approach my principal to name the week of May 27 to June 2 Aids Education Week. Subsequently, I wrote Governor Whitman asking her to proclaim the week as a statewide event. In short order, Governor Whitman responded by sending me a formal proclamation. The week was one which included discussions on the topic from teachers of all subjects. The educational aspect of the week ended with a three hour assembly with guest lecturers such as Dr. James Oleske, the preeminent pediatric Aids authority in America. The week's activities culminated with an Aids Walk on Sunday June 2. All monies raised went to the Starfish Foundation for Children with Aids.

I was pleasantly surprised to receive a commendation from Senator Lautenberg in the Congressional Record. The joint New Jersey Senate and Assembly also honored

me with a formal resolution. Through the efforts of Senator Bradley's office, your office sent me a copy of your World Aids Day Proclamation. While I appreciate the effort, I must admit that I do not understand the significance of this document to my project. Just today I reread this proclamation very thoroughly. It seems to focus on most of the important issues relative to HIV/Aids, but does not address the educational angle at all.

It is critical that your office accept my suggestion and proclaim an AIDS EDUCATION WEEK in the United States. Education must be the first line of defense in the war against this deadly disease. The best way to prevent the spread of HIV/Aids is to educate the youth of this country. It is important that you take your place in history as the President who educated America's youth in this regard.

My commitment to this cause has become an important part of my existence. Perhaps you would consider appointing me as a member of one of your Aids Councils. Please take my message seriously for the betterment of the future of this country.

The dates for the Aids Education Week in New Jersey for 1997 will be May 26 to June 1. It is my intention to involve my fellow students from all over the state, both in the educational and fundraising aspect of this important week.

I look forward to your reply.

Respectfully yours,

Jessica Pomerantz
20 Michele Court
Cresskill, New Jersey 07626
201-894-1562
201-894-8287 (fax)

Office of
National AIDS Policy

Correspondence Routing Slip

Tracking Number: 63671

Date Rcvd: 04-21-97

From: Stanley C. Erck
Procept

Staff Action:

Reviewed By Sandy: _____ Reviewed By: _____

Assigned To: _____

RCVD: _____ DONE: _____

Recommendations/Instructions:

Info

To Support Staff: _____

Date of Response: _____



Procept, Inc.
840 Memorial Drive
Cambridge, MA 02139
TEL: 617-491-1100
FAX: 617-491-9019

April 16, 1997

Ms. Sandy Thurman
The White House Director of AIDS Policy
808 17th Street, N.W., 8th Floor
Washington, DC 20006

Dear Ms. Thurman:

Congratulations on your recent appointment to director of National AIDS Policy. I was pleased to hear of your commitment to stopping the transmission of HIV. At Procept, a biotechnology company involved in discovering drugs for immune system disorders and AIDS, we are actively developing a topical microbicide to address this need. The road to an effective topical microbicide will be long, and will require the cooperation of many groups. I believe that our effort will benefit from the resources and enthusiasm of the current administration.

I thought you would be interested in learning about Procept's ventures in this area. We are developing a drug, PRO 2000, for use in a topical microbicide for preventing infection by HIV and other STDs. PRO 2000 has been shown to be effective against a variety of HIV strains and also to prevent infection by herpes simplex viruses that cause genital lesions.

We are in the process of conducting Phase I clinical trials and based on the results, anticipate further studies to demonstrate safety and efficacy in populations at high risk for HIV infection.

We are aware of the urgent need for a topical microbicide such as ours. We have made the PRO 2000 topical microbicide program our highest priority. As a biotechnology company with limited resources, we will need the infrastructure and financial commitment of the U.S. Government to move through the lengthy development process. We look forward to the opportunity to work closely with you and to the day when we can announce the approval of a new weapon against HIV infection.

I have included an information package describing our work, and would be pleased to personally brief you and/or other interested groups about our efforts if you think it appropriate. In addition, we welcome any suggestions that you may have that would help Procept in funding and executing this important development effort.

Sincerely,

A handwritten signature in black ink, appearing to read "Stanley C. Erck".
Stanley C. Erck
President and CEO

/ec
Enclosure

PRO 2000 TOPICAL MICROBICIDE PROGRAM

SUMMARY

Background and Rationale

Infection by the human immunodeficiency virus type 1 (HIV-1), the causative agent of AIDS, continues to spread at epidemic proportions in many parts of the world. The World Health Organization recently estimated that more than 70% of new infections are acquired through heterosexual intercourse, and rates of heterosexual transmission are increasing in the United States and other Western countries. While a heterosexual HIV-1 epidemic does not appear imminent in the United States, fear of infection remains widespread.

There is a critical need for new strategies to prevent HIV-1 transmission, especially in the absence of an effective vaccine. While condoms offer an effective barrier against HIV-1 infection and other sexually transmitted diseases (STD's), rates of consistent and correct use are low. Furthermore, condom use requires the consent of the male partner, which cannot always be negotiated by female partners at risk for infection. There is therefore a need for new and acceptable prevention technologies that are under the personal control of women. "Topical microbicides" that provide a chemical barrier to infection offer an appealing approach, and their development is now a high priority of the U.S. Government and international agencies (Figure 1).

PRO 2000: Physical and Chemical Properties

Procept has identified a new antiviral compound, PRO 2000, that is particularly well suited for use as a topical microbicide to prevent transmission of HIV-1 and other STD pathogens (Figure 2). The compound is a naphthalene sulfonic acid polymer of about 5000 molecular weight, is easy to manufacture, and is stable for at least a year at room temperature (Figure 3). Unlike related compounds, it is virtually colorless, but can be easily monitored in biological fluids by ultraviolet absorbance or fluorescence (Figure 4). Patent applications have been filed on PRO 2000 and its use as a topical microbicide.

Antiviral Activity of PRO 2000

In assays performed at Procept and several leading laboratories, PRO 2000 blocked infection by a wide range of HIV-1 isolates (Figure 5). The compound, for example, showed potent activity against three primary clinical isolates (Figure 6). Importantly, PRO 2000 also prevented the infection of fresh macrophages by isolates that are resistant to other polyanions such as dextran sulfate (Figure 7). PRO 2000 also inhibited infection by two African isolates (Figure 8), suggesting utility in an African population at high risk for heterosexual HIV-1 transmission. PRO 2000 was found to be over ten times more potent, and less cytotoxic, than the commercial spermicide nonoxynol-9, which is currently being evaluated as a topical microbicide (Figure 9).

Activity Against other STD Pathogens

PRO 2000 also shows activity against herpes simplex viruses (types 1 and 2) and human cytomegalovirus (Figure 10). Genital herpes is epidemic in the United States, and lesions associated with the disease are believed to facilitate HIV-1 transmission. Suppression of herpes infection would therefore be an attractive attribute of a topical microbicide. Activity against other STD pathogens, including *Chlamydia trachomatis*, *Neisseria gonorrhoeae*, and *trichomonas vaginalis* is under evaluation.

Mechanism of Action

PRO 2000 interferes with the initial steps of HIV-1 infection: viral attachment and membrane fusion. The compound was shown to block the binding of the viral envelope glycoprotein gp120 to the cellular CD4 receptor, a property that distinguishes it from dextran sulfate (Figure 11). PRO 2000 also binds tightly to recombinant CD4 in solution (Figure 12). Because CD4 is a highly conserved, nonmutable protein, a mechanism involving CD4 blockade would be expected to limit the ability of the virus to develop resistance. Normal antigen-dependent T-cell proliferation is not affected at concentrations that suppress HIV-1 infection.

Infection by herpes simplex virus and other STD pathogens involves the attachment of anionic sulfated glycans to cellular or viral receptor proteins. PRO 2000, by virtue of its anionic character, would be expected to block these interactions, and this effect may explain the compound's observed anti-herpes activity.

Clinical Evaluation of Intravenous PRO 2000

Systemic PRO 2000 is currently being evaluated as a therapy for HIV-1 disease. To enable clinical testing, the toxicology and pharmacokinetics of daily bolus injections were evaluated in rodents (up to 90 days) and primates (up to 28 days). The compound is not mutagenic, and shows negligible arterial and venous irritation in rabbits. Oral absorption was found to be low.

A Phase I clinical trial was conducted to assess the tolerability and pharmacokinetics of single intravenous doses in healthy, HIV-negative volunteers. Doses of up to 1.2 mg/kg caused no clinical adverse events, and peak plasma levels exceeded the concentrations required to block HIV-1 infection *in vitro*. A Phase I/II "proof-of-principle" trial to assess the effect of daily 1.2-mg/kg bolus injections on viral load in HIV-positive patients is underway.

Preclinical Evaluation of a PRO 2000 Topical Microbicide

A PRO 2000-containing vaginal gel formulation has been developed and evaluated in several preclinical studies. Gels containing 0.1%, 1.0% and 4.0% PRO 2000 were tested for vaginal irritation in a rabbit model, along with the gel vehicle and a nonoxynol-9-containing spermicide. Though all of the gels showed acceptable levels of irritation, microscopic assessment of vaginal specimens revealed that the PRO 2000 gels caused

much less epithelial erosion than the nonoxynol-9 product (Figure 13). Epithelial disruption could potentially enhance the risk of HIV-1 infection, and the pathologist concluded in his report that the "lessened epithelial damage associated with PRO 2000 gel may represent a significant clinical advantage over N-9". Importantly, PRO 2000 was not detected in the plasma following vaginal administration.

PRO 2000 was also tested for skin sensitization in a standard guinea pig model. No sensitization was observed (Figure 14).

PRO 2000 gel was also shown to be compatible with latex condoms. Treatment of unlubricated condoms with 4% PRO 2000 gel had no effect on physical properties or airburst parameters (Figure 15).

The spermicidal activity of PRO 2000 is currently under evaluation.

Clinical Evaluation of PRO 2000 Topical Microbicide

Phase I clinical trials to assess the safety of PRO 2000 vaginal gels will soon be underway at two sites in Europe (Figure 16). One study will be conducted at the Institute of Tropical Medicine in Antwerp, Belgium, under the direction of Drs. Marie Laga and Lut van Damme. The study was initiated in November, 1996 following notification of Ethics Committee approval. A parallel Phase I study is scheduled to begin shortly at St. Mary's Hospital in London under the direction of Drs. Jonathan Weber and Valerie Kitchen. This trial will be conducted under the auspices of the British Medical Research Council (MRC).

If the gels are well tolerated in the two Phase I studies, we plan to conduct a series of Phase I/II trials to assess safety in diverse populations, including groups at high risk for STD infection. This would be followed by a Phase III trial to evaluate efficacy. Discussions are underway with the NIH, MRC, and other agencies to secure support for this clinical program (Figure 17).

Summary

To summarize, we feel there is a strong rationale for the development of a topical microbicide based on PRO 2000:

- 1) New, acceptable, and female-controlled technologies to prevent transmission of HIV-1 and other STD pathogens are needed.
- 2) Development of topical microbicides has been endorsed by the U.S. Government, the British Medical Research Council, and the Joint United Nations Programme on HIV/AIDS.
- 3) PRO 2000 blocks infection by a wide range of HIV-1 isolates *in vitro*. Activity against macrophage-tropic isolates distinguishes PRO 2000 from other polyanions.
- 4) PRO 2000 blocks initial attachment of HIV-1 to the CD4 receptor, and this mechanism of action may limit the ability of the virus to develop resistance.

- 5) PRO 2000 blocks infection by herpes simplex virus type 2, the causative agent of genital herpes. This activity is probably due to competition for viral attachment to anionic cell surface glycans, and a similar mechanism could suppress infection by other STD pathogens.
- 6) PRO 2000 is synthesized by a simple process, suggesting that large quantities can be manufactured for reasonable cost.
- 7) PRO 2000 is highly stable.
- 8) Extensive animal data, as well as human clinical data, are available on the systemic use of PRO 2000.
- 9) PRO 2000 is non-mutagenic and non-sensitizing.
- 10) PRO 2000 gel was well tolerated in a rabbit vaginal irritation model.
- 11) PRO 2000 is not detectable in plasma following topical administration.
- 12) PRO 2000 gel is compatible with latex condoms.
- 13) Phase I clinical testing of PRO 2000 vaginal gel is underway.

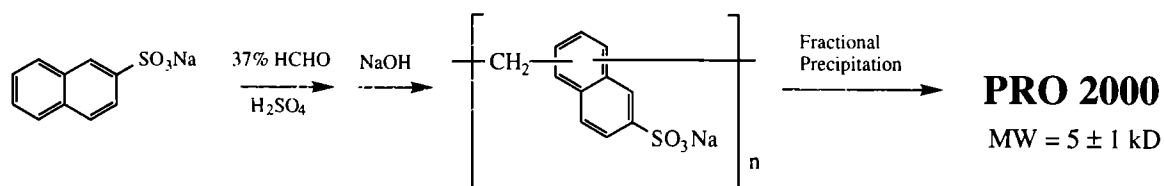
Figure 1. Need for new and acceptable HIV-1 prevention technologies.

- Worldwide, most HIV transmission is through heterosexual intercourse.
- Fear of HIV infection (and other STD's) is widespread.
- Condoms are effective, but not used consistently:
 - inconvenient and unappealing
 - use controlled by male partner
- Development of new and acceptable female-controlled prevention technologies is a high priority for national and international agencies.

Figure 2. Suitability of PRO 2000 for use as a topical microbicide.

- Active against a wide range of HIV-1 isolates
- Active against herpes and human cytomegalovirus
- Inexpensive to produce
- Stable
- Sensitive assay available
- Data on systemic use available (animal and human clinical studies)
- Topical gel well tolerated in rabbit vaginal irritation model
- Non-sensitizing
- Compatible with latex condoms

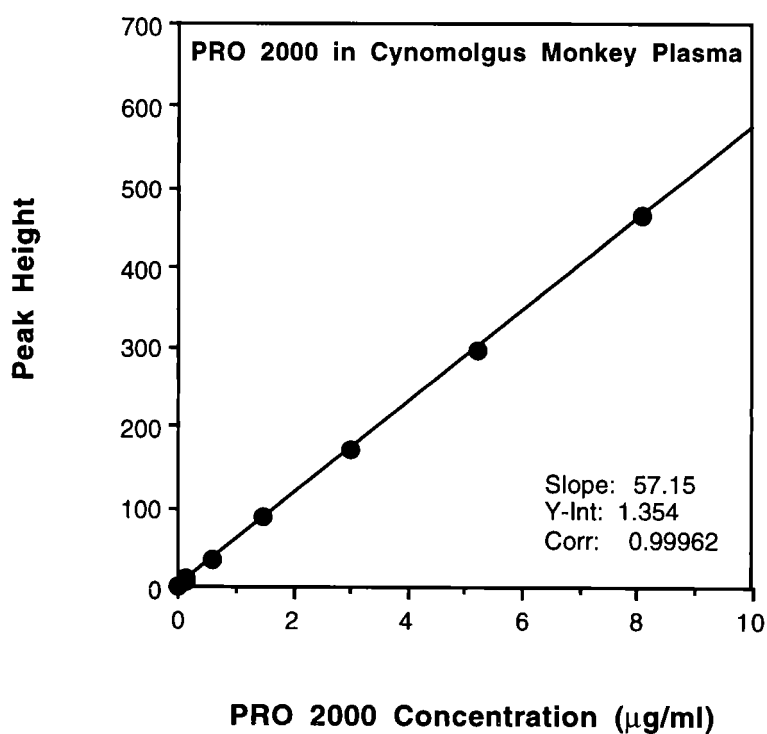
Figure 3. GMP synthesis of PRO 2000.



- GMP manufacturing process implemented
- Current scale: 120 grams per batch
- *Bulk and solutions* stable for ≥ 12 months at 40°C

Figure 4. HPLC method for PRO 2000 determination in biological fluids.

- Samples are treated with detergent to dissociate bound protein and separated by HPLC. PRO 2000 is detected by intrinsic fluorescence at 355 nm.
- Experimental limit of quantitation: $\sim 1 \mu\text{g/ml}$.
- Response linear:



- Heat inactivation does not affect response.
- Validated for human and animal plasma. Validation in vaginal lavage underway.

Figure 5. Anti-HIV-1 activity of PRO 2000.

Syncytium-inducing (SI) and nonsyncytium-inducing (NSI) isolates were used to infect CD4⁺ T-cell lines, fresh human peripheral blood mononuclear cells (PBMC's) or fresh human macrophages. Assays were performed by five different laboratories. Fifty-percent inhibitory concentrations (IC₅₀s) fall within a narrow range.

Isolate	Phenotype	Target Cells	IC ₅₀ (µg/ml)
<i>Laboratory-adapted Isolates</i>			
IIIB	SI	CEM, H9 Lines	0.5 - 2.5
RF	SI	CEM Line	3.5
<i>Clinical Isolates</i>			
JR-CSF	NSI	PBMC's	1.5
14a-Pre	NSI	PBMC's	10
N70	NSI	PBMC's	4.0
WEJO	SI	PBMC's	0.9
BAKI	SI	PBMC's	1.6
VIHU	NSI	PBMC's	2.1
<i>Monocytotropic Isolates</i>			
ADA		Macrophages	0.30
BaL	SI	Macrophages	1.2
SLKA	NSI	Macrophages	6.1
<i>African Isolates</i>			
UG/92/029 (Clade A)	SI	PBMC's	0.31
UG/92/021 (Clade D)	SI	PBMC's	0.52

Figure 6. Activity of PRO 2000 against HIV-1 clinical isolates.

PRO 2000 inhibited infection of fresh human PBMC's by primary (single-passage) clinical isolates WEJO, BAKI, and VIHU. Activities against each of these isolates were similar to the activity against infection of CEM-SS cells by the laboratory-adapted isolate HIV-1 IIIB. In these experiments, no cytotoxicity was observed at the highest concentrations tested.

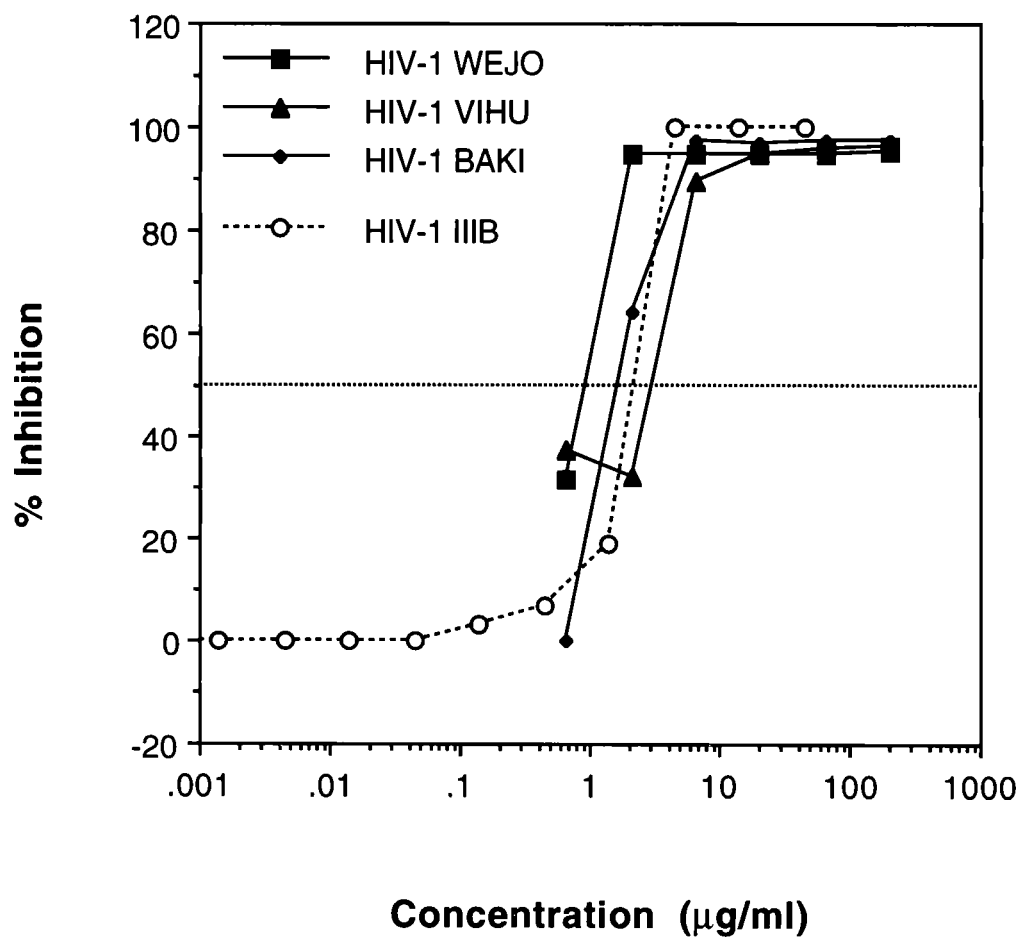


Figure 7. Activity of PRO 2000 against monocytotropic HIV-1 isolates.

PRO 2000 suppressed the infection of fresh human macrophages by monocytotropic isolates SLKA and ADA (in collaboration with Drs. N. Sarver and S. Bridges, DAIDS, NIAID). Monocytotropic isolates have been reported to be resistant to dextran sulfate (Meylan *et al.*, *Antimicrob. Agents Chemother.* **38**, 2910-6, 1994).

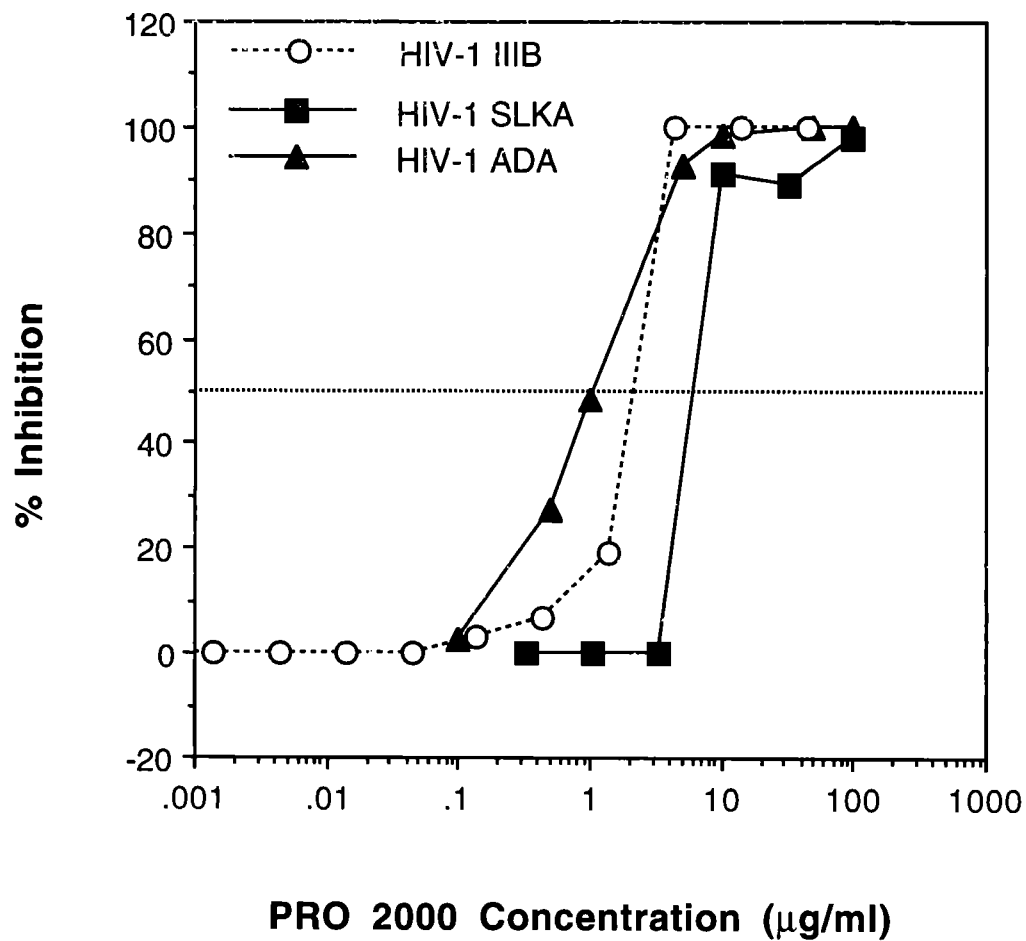


Figure 8. Activity against African HIV-1 isolates.

PRO 2000 suppressed the infection of fresh PBMC's by two isolates of African origin. The isolates belong to subtypes A and D, respectively.

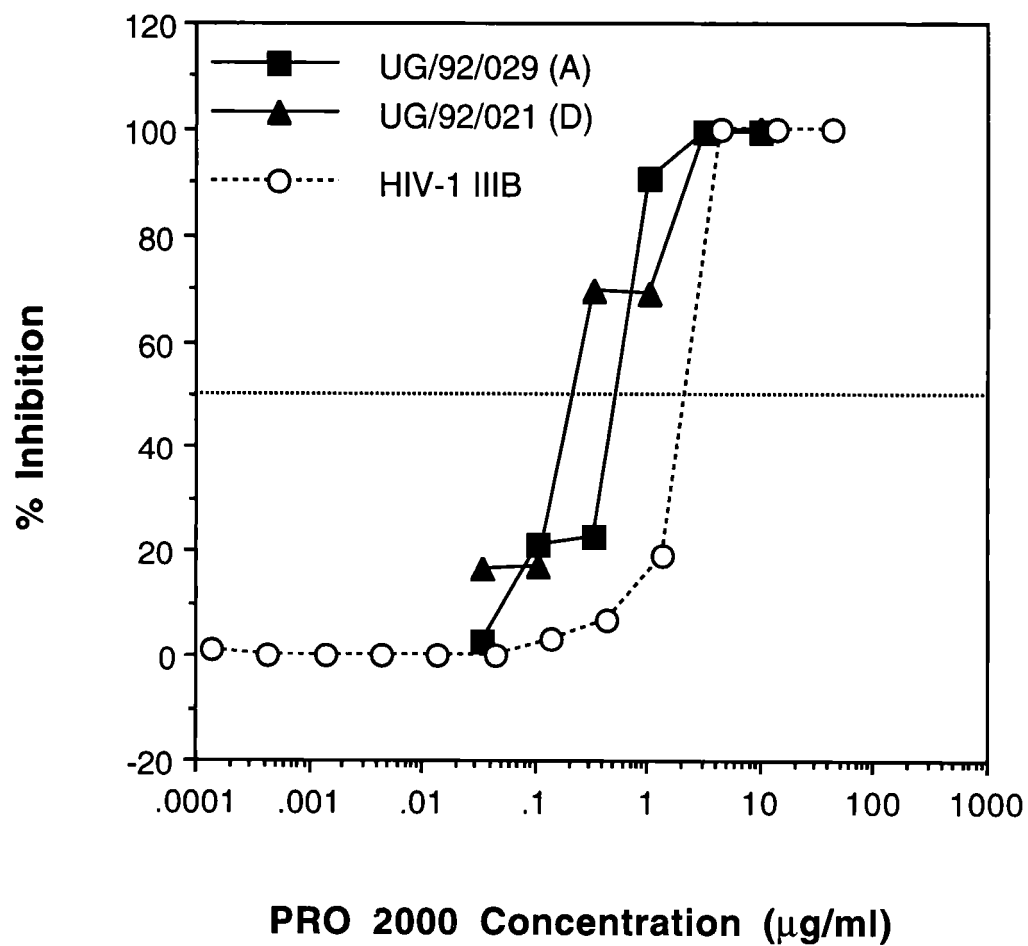


Figure 9. Inhibition of HIV-1 infection by PRO 2000 and Nonoxynol-9.

PRO 2000 inhibited HIV-1_{IIIB} infection of C8166 T-lymphoblastoid cells more effectively than the common spermicide nonoxynol-9. The apparent antiviral effect of nonoxynol-9 may have been due to cytotoxicity (as measured by [¹⁴C]-amino acid incorporation). PRO 2000 showed no cytotoxicity at 100 µg/ml. Assays were performed by Dr. D. J. Jeffries, St. Bartholomew's Hospital, London with support of Dr. A. Stone, Medical Research Council, United Kingdom.

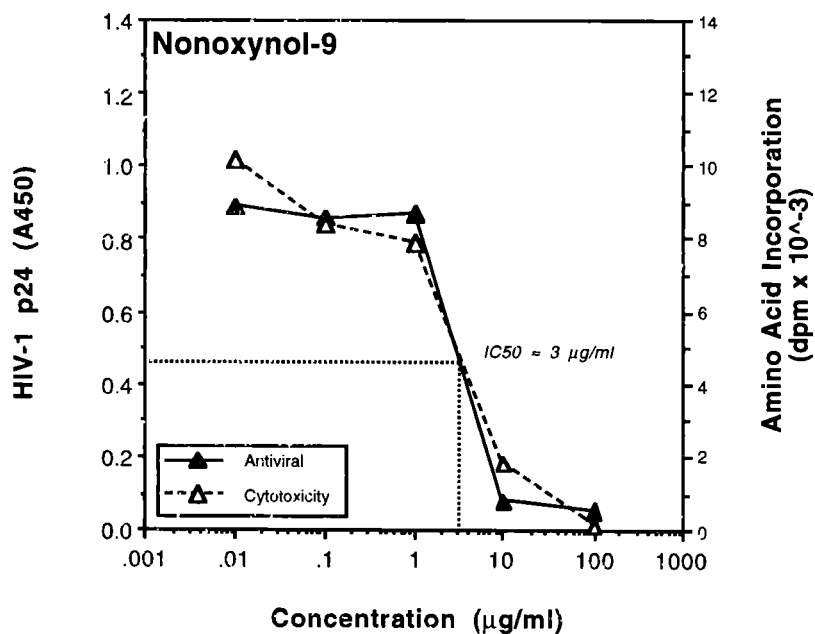
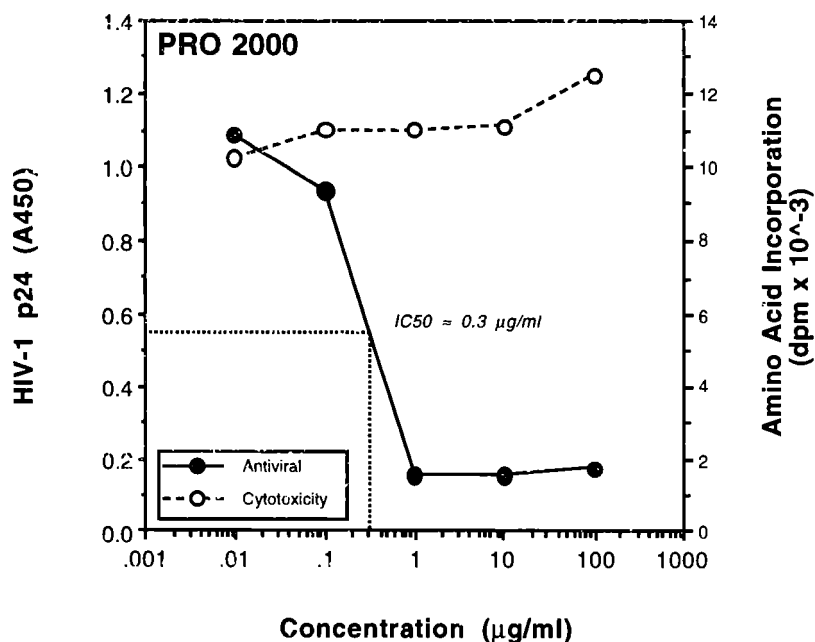


Figure 10. Inhibition of herpesviruses by PRO 2000.

PRO 2000 inhibited infection of human embryonic fibroblasts by herpes simplex virus (HSV) types 1 and 2 and human cytomegalovirus (HCMV) in a plaque reduction assay. HSV-2 is most commonly associated with genital herpes.

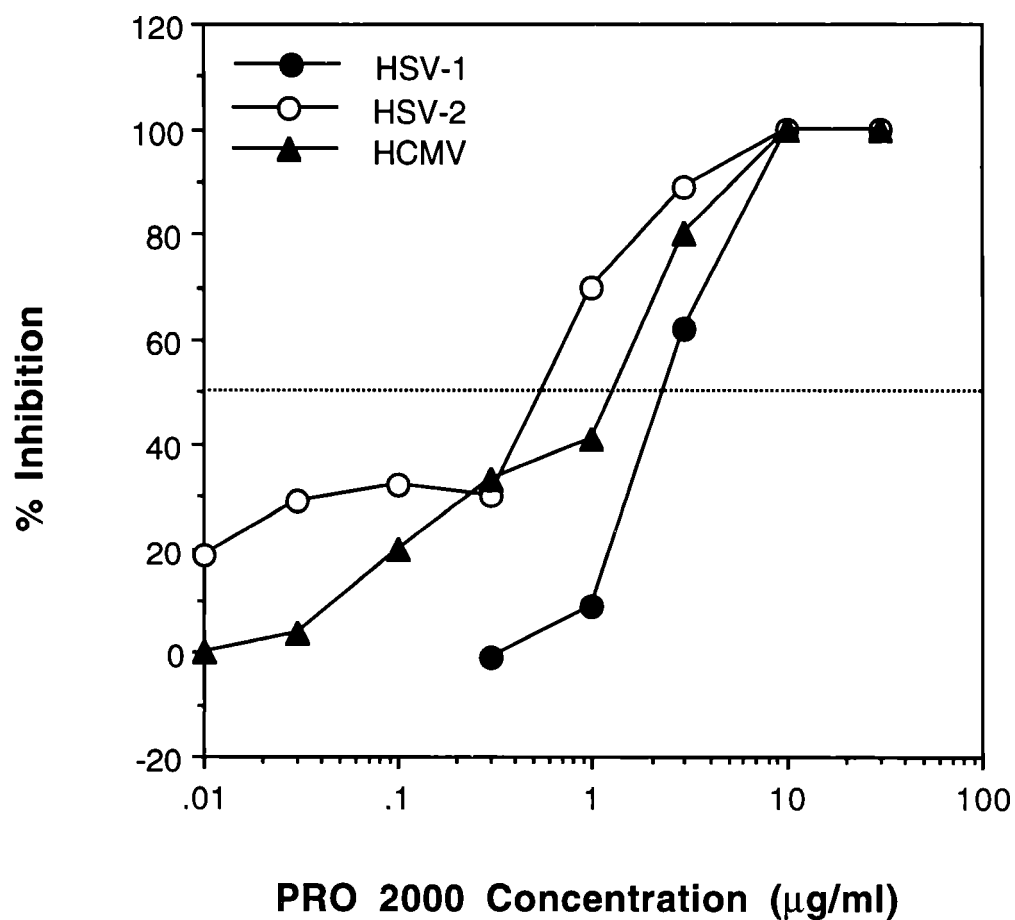


Figure 11. Inhibition of recombinant gp120 binding to recombinant CD4.

PRO 2000 inhibited [^{125} I]-labeled gp120 binding to CD4 in a radiometric bimolecular assay system. Dextran sulfate was much less potent in the assay.

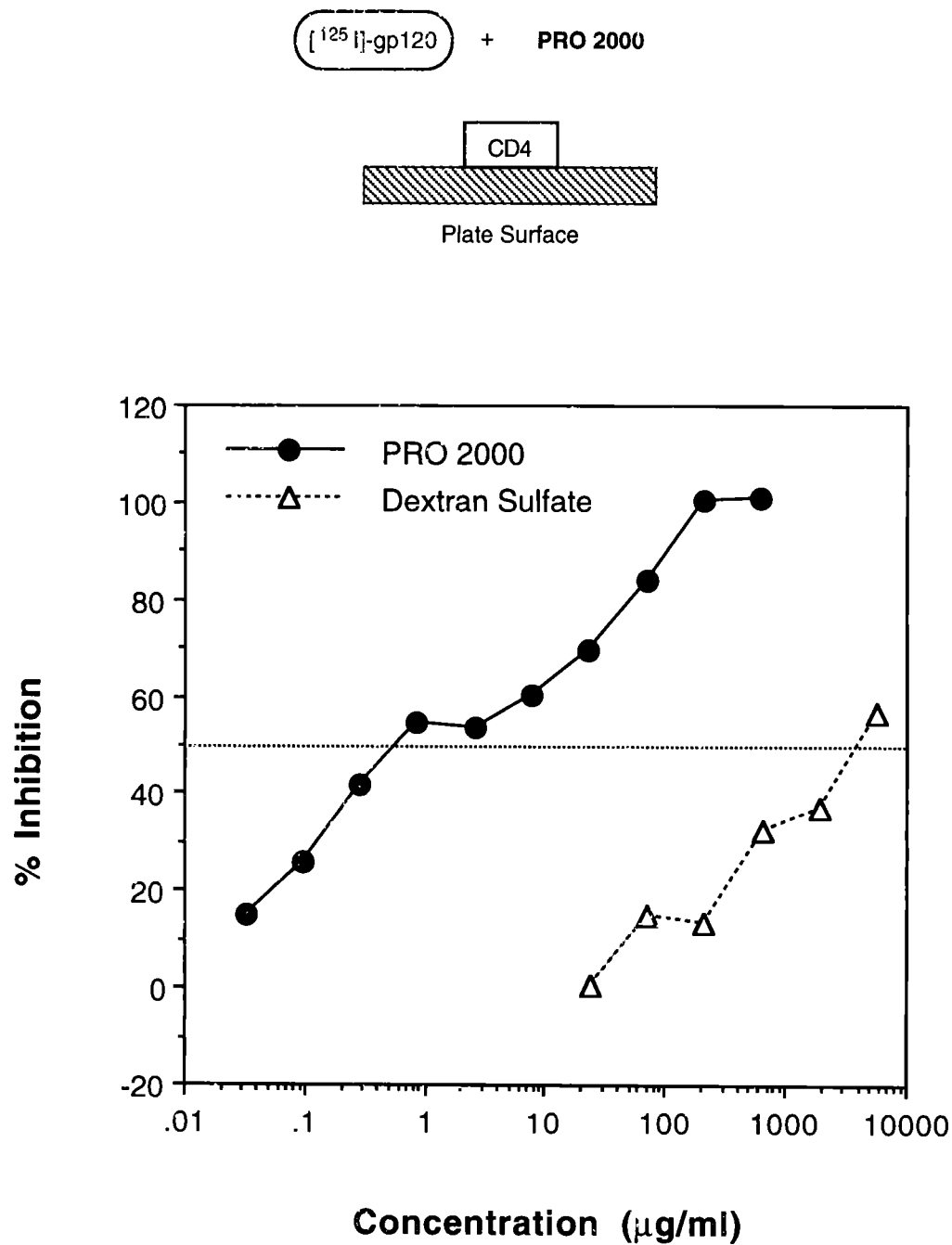


Figure 12. Tight binding of PRO 2000 to recombinant, soluble CD4.

Recombinant, soluble CD4 (domains 1 and 2) quenched the intrinsic fluorescence of PRO 2000. Inset: Titration with CD4 led to saturable binding. A nonlinear fit of the data to a simple bimolecular binding model gave an apparent dissociation constant of ~ 20 nM and a stoichiometry of 1:1.

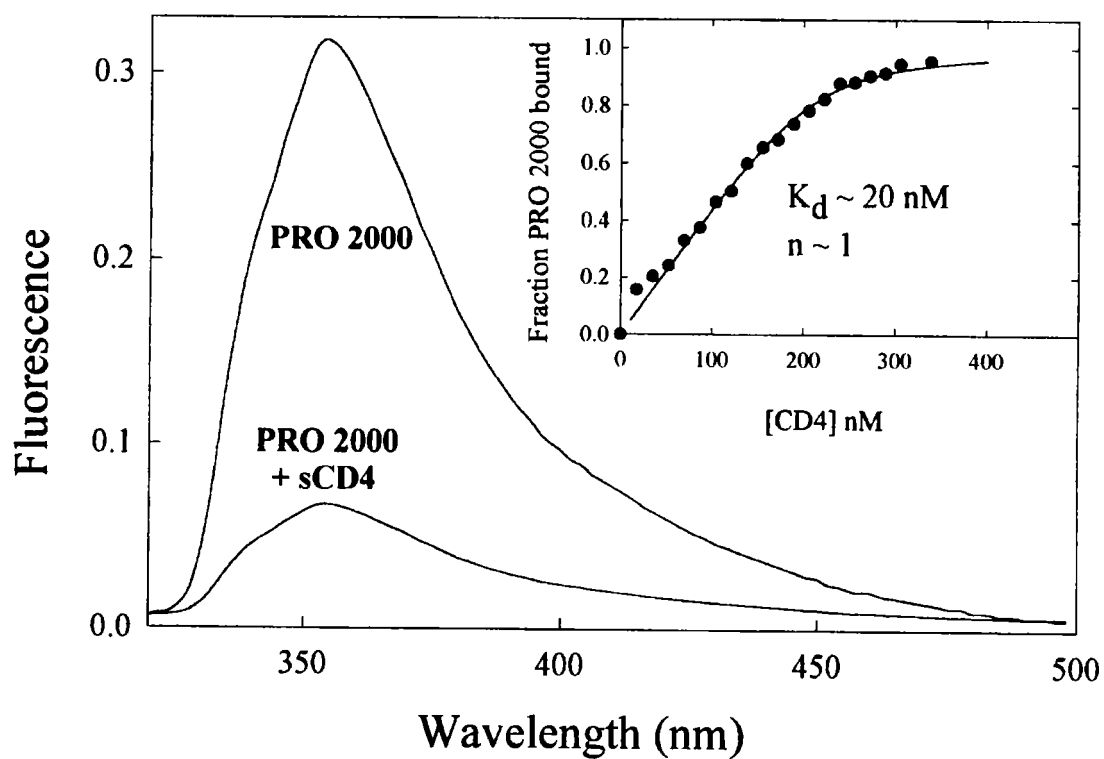


Figure 13. Vaginal irritation in rabbits.

PRO 2000 or control gels (1 ml) were administered vaginally to female New Zealand White rabbits once per day for 14 days. Following sacrifice (~24 hours post-dosing), vaginal sections were assessed microscopically and scored for epithelial irritation, vascular congestion, leukocyte infiltration, and edema. Combined scores of 11.5 or less are considered acceptable; scores for PRO 2000 gels were less than for an OTC nonoxynol-9 product. Incidence of epithelial focal erosion (grade 3) or generalized erosion/ulceration (grade 4) in vaginal tissue samples was much lower for the PRO 2000 gels than for the nonoxynol-9 product. PRO 2000 in plasma 1 hr post-dosing was determined by an HPLC method.

Test Article	N	Irritation Score	Epithelial Erosion ¹	PRO 2000 in Plasma
Placebo gel	5	5.4	0/15	<ELOQ ²
0.1% PRO 2000 gel	5	6.1	0/15	<ELOQ
1.0% PRO 2000 gel	5	8.1	1/15	<ELOQ
4.0% PRO 2000 gel	5	7.0	1/15	<ELOQ
4% Nonoxynol-9 gel	5	8.4	7/15	<ELOQ

¹ Incidence of focal erosion (grade 3) or generalized erosion/ulceration (grade 4)

² ELOQ = Experimental Limit of Quantitation (1.5 µg/ml)

Figure 14. PRO 2000 does not induce skin sensitization.

Young adult Hartley guinea pigs ($N = 12$) were exposed to 4% PRO 2000 gel under an occluded patch for 6 hr at weeks 0, 1 and 2. A challenge treatment of 1% PRO 2000 gel was applied similarly at week 4. Irritation was scored 24 and 48 hr post-dosing (*).

No skin sensitivity was observed.

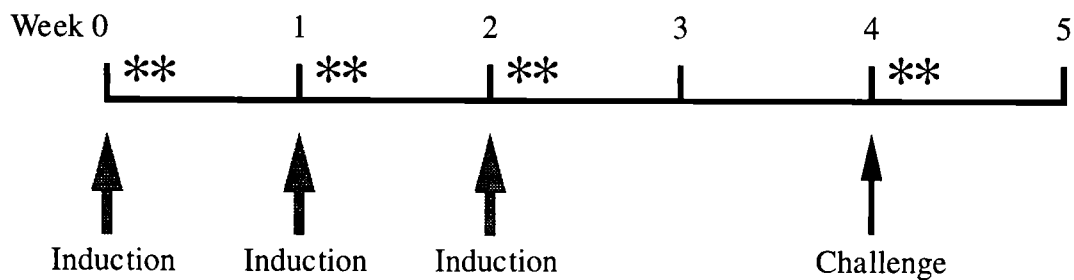


Figure 15. PRO 2000 is compatible with latex condoms.

Unlubricated Trojan-ENZ[®] condoms (Carter-Wallace, Inc.) were treated with 4% PRO 2000 gel and placed at 37° C, 95% relative humidity for 30 min. They were then washed, dried, and tested for physical properties and airburst parameters (ASTM D 3492-93, PARA. 6.2, 6.3).

Test	Unexposed	Exposed
<i>Physical Properties:</i>		
Elongation (%)	800 ± 19.4	801 ± 12.3
Tensile Strength (MPa)	26.8 ± 2.2	26.5 ± 2.1
<i>Airburst:</i>		
Pressure (kPa)	2.0 ± 0.24	1.9 ± 0.24
Corrected volume (l)	39.3 ± 8.26	38.3 ± 6.32

Figure 16. Phase I clinical trials of PRO 2000 Topical Microbicide.

Institute of Tropical Medicine, Antwerp, Belgium

- Drs. Marie Laga and Lut van Damme
- Study approved by Ethics Committee
- Study initiated November 15, 1996

St. Mary's Hospital, London, England

- Drs. Valerie Kitchen and Jonathan Weber
- Submitted to Ethics Committee
- Supported through MRC collaborative agreement
- Scheduled initiation: Q1, 1997

Figure 17. Potential agency support for PRO 2000 topical microbicide clinical program.

- **NIH** (Drs. Penelope Hitchcock, Zeda Rosenberg)
 - Ongoing relationship with DAIDS
 - NIAID-supported antiviral testing underway
 - Potential clinical trial support

- **MRC** (Dr. Alan Stone)
 - Collaborative Agreement signed October, 1996
 - \$1 million to Phase I clinical trial site
(St. Mary's Hospital, London)

- **UNAIDS** (Dr. Jos Perriens)
 - Recommended Antwerp clinical site

Office of
National AIDS Policy

Correspondence Routing Slip

Tracking Number: G3675

Date Rcvd: 04-23-97

From: Leonardo R. Ortega, M.D.
Hepo AIDS Walk

Staff Action:

Reviewed By Sandy: _____ Reviewed By: _____

Assigned To: _____

RCVD: _____ DONE: _____

Recommendations/Instructions:

Invitation

To Support Staff: _____

Date of Response: _____

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86



18 April 1997

Sandy Thurman, Director
Office of National AIDS Policy
Executive Building
The White House
1600 Pennsylvania Avenue
Washington, D.C. 20503

Dear Ms. Thurman:

On behalf of the Health Education Resource Organization's Board of Directors, staff and volunteers, it is with great enthusiasm that I congratulate you on your appointment as Director of the Office of National AIDS Policy by President Clinton.

Having headed a community-based AIDS service organization, such as HERO, we know that you are aware of the importance of public and private partnership to fight the AIDS epidemic and the urgent need to increase the AIDS policy within the White House.

I would also like to extend an invitation for you to join us for HERO AIDS WALK '97, in the morning of Sunday, June 8, 1997. Dan Gilbert, a HERO Board of Directors member, will be contacting you regarding this matter.

HERO wishes you great success in your new position. Please do not hesitate to contact our office, if we can be of any assistance to you.

Sincerely,

Leonardo R. Ortega, M.D., M.P.H.
Executive Director/CEO

/amh

Encl.





DEPARTMENT OF HEALTH & HUMAN SERVICES

Office of the Secretary

Office of International Affairs
Washington, D.C. 20201

April 16, 1997

[Handwritten signature]
4/16/97

FAX FOR SANDY THURMAN

FROM: David Hohman *[Signature]*

Attached are the papers that we sent to Dan Tarullo for the last G-7 Sherpa meeting on HIV/AIDS.

Also attached is a memo I sent today regarding the "underfunded" issue.

I'll keep you informed as this progresses.

Attachments - 13 pages

708 1934
x4619
— *[Signature]*



March 28, 1997

MEMORANDUM FOR BILL ANTHOLIS

FROM : David E. Hohman
Director, OIA

SUBJECT: Briefing Materials for Denver Summit Sherpa Meeting

Attached are papers for the upcoming Denver Summit Sherpa meeting on April 6-7:

1. Scope Paper: HIV/AIDS, with background paper on UNAIDS.
2. Talking Points/Background: International AIDS Vaccine Research Initiative.
3. Talking Points/Background: Joint United Nations Program on HIV/AIDS.

These papers have been cleared by HHS, OSTP, and Treasury.

The papers were provided to State (Peter Chase and OES), DPC (Office of National AIDS Policy/EGoosby) - no response was received.

A diskette in Microsoft Word format is also attached.

If you have any questions about these papers, please call me on 690-6174.

HIV/AIDS

Proposal for an International AIDS Vaccine Research Initiative

The Need for an AIDS Vaccine

A safe and effective AIDS vaccine is a global public health imperative. More than 29 million men, women, and children around the world have been infected with HIV. More than 3 million of these infections occurred in just the past year, with nearly 95% in the poorest parts of the world. AIDS has brought about a significant decline in overall life expectancy in many African countries, threatening the economies of these already poor nations and robbing them of their workforce. Without an effective vaccine, AIDS will soon overtake tuberculosis and malaria as the leading infectious cause of death in the world. Even among the industrialized nations, where anti-HIV therapies are available, complacency is not an option. HIV is capable of mutating and becoming resistant to therapies, and could well become even more dangerous. Only a truly effective preventive anti-HIV vaccine can limit and eventually eliminate the threat of AIDS.

Whereas formidable scientific obstacles have impeded the development of an HIV vaccine in the past, new advances in immunology and recent dramatic progress in understanding how HIV causes infection create an unprecedented opportunity. With vigorous scientific effort, HIV vaccine development should be within our grasp.

Ongoing International Collaboration

Cooperation among scientists, governments, non-governmental organizations, and international agencies can hasten the development of an effective AIDS vaccine for the benefit of all nations. Some of the Eight participate in active programs of international collaboration and cooperation, as do countries severely affected by HIV/AIDS. Many of us have bilateral agreements that include AIDS research efforts, and many of our institutions and scientists have close informal working relationships.

HIV vaccine research is of major importance in the U.S. agreement with France (NIH-INSERM Biomedical Research Agreement) and in informal arrangements with scientific institutions in the U.K. and Canada. A number of other agreements emphasize cooperation in basic research areas that can lead to the development of new and novel approaches for the design of a preventive HIV vaccine. A U.S.-Indo Vaccine Action Program has been established under the auspices of the U.S.-India bilateral agreement that places a high priority on the inclusion of HIV vaccines under its development plans. Collaborative agreements regarding AIDS research also exist between other nations, such as Japan and France.

NIH AIDS Vaccine Initiatives

President Clinton's FY 1998 budget calls for \$150 million for HIV vaccine research, an increase of 33.6% over the FY 1996 appropriation. NIH has appointed distinguished scientists to an AIDS Vaccine Research Committee to provide new leadership to the NIH HIV vaccine effort. The Committee is already engaged in international collaboration.

Proposal for International Initiatives

It is proposed that the Eight make a political commitment to providing, in their own countries, the investments necessary to accelerate research toward the development of an HIV/AIDS vaccine as a scientific and public health priority. Scientific collaboration and cooperation could be enhanced through the AIDS Vaccine Research Committee of the U.S. National Institutes of Health.

The Director of the U.S. National Institutes of Health could consult with his counterparts in the Eight prior to the Summit about this proposal. The purpose of this consultation would be to determine the areas where additional efforts would be most productive and where additional scientific collaboration and cooperation would benefit vaccine research. The recommendations resulting from this consultation could be available for consideration at the Summit.

To provide continuity and to monitor scientific progress, key scientists from nations that have made a significant investment in AIDS vaccine research could meet on an annual basis, or more often as necessary, in concert with the U.S. NIH AIDS Vaccine Research Committee. This group would discuss research progress, identify scientific gaps and opportunities, design collaborative programs aimed at utilizing the unique scientific and clinical resources of each participant, and share scientific information. The primary role of this group would be to address the scientific issues related to the development of AIDS vaccine candidates for worldwide use.

An important international cooperative activity, mediated through the UNAIDS Vaccine Advisory Committee, can assist this effort in the development of international sites for vaccine research and testing and in involving scientists in host countries in these research areas. UNAIDS has also established a committee to address the legal and ethical issues related to AIDS vaccine research. Policy issues that may arise from AIDS vaccine research could be addressed by these groups, which have mechanisms to bring together international policy makers.

A greater worldwide investment in AIDS vaccine research, together with international collaborative efforts, where appropriate, promise to speed us toward the goal of developing a protective HIV vaccine.

UNAIDS

The Joint United Nations Program on HIV/AIDS (UNAIDS) is the body within the United Nations system responsible for leading a global effort to expand the scale and quality of the response to HIV/AIDS. The principle behind the creation of UNAIDS was, and continues to be, that HIV/AIDS is not just a health issue, but rather an issue involving economics and development, education, and other sectors of society and government. The Eight were major advocates for the creation of UNAIDS.

UNAIDS is an important example of UN reform in action. The first "virtual" UN organization, it provides centralized policy, international best practices, and advocacy. The co-sponsoring and other UN agencies develop and implement programs, providing synergy, policy coordination, and a reduction in administrative costs.

UNAIDS' efforts to prevent and control HIV/AIDS remain woefully underfunded. The Eight have provided \$35 million for the 1996-97 biennium toward the approved budget of \$120 million. Although UNAIDS will meet its budget from other donors and carry-over funds from the old WHO Global Program on AIDS, core funding for the 1998-99 biennium is a critical need.

It is also important to increase funding for the "Coordinated Appeal for Supplemental Activities." This coordinated appeal is for \$18 million requested for (and by) the six co-sponsors for specific AIDS activities. This fund, and the activities, are coordinated by UNAIDS. It increases UNAIDS' credibility and enables UNAIDS to provide funds for country-level operational efforts.

The Eight could openly recognize the severity of HIV/AIDS globally and make a commitment to provide funding for UNAIDS, both core support and the global supplementary funding appeal.

Background Paper

JOINT UNITED NATIONS PROGRAM ON HIV/AIDS (UNAIDS)

UNAIDS, which came into formal existence in January 1996, is jointly sponsored by the World Health Organization, the United Nations Children's Fund, the UN Population Fund, UNESCO, the United Nations Development Program, and the World Bank, each of which provides some support to the organization.

Headquartered in Geneva, UNAIDS is headed by an Executive Director, Dr. Peter Piot (Belgium).

The governing body of UNAIDS is called the Program Coordinating Board (PCB). Current members of the PCB are Algeria, Barbados, Bulgaria, China, Japan, Netherlands, South Africa, Sweden, United Kingdom, Congo, France, India, Pakistan, Paraguay, Russia, Uganda, and the United States. Representatives of five non-governmental organizations are also on the PCB.

The principal functions of UNAIDS are to:

- Provide global leadership in the response to HIV/AIDS;
- Achieve and promote global consensus on policy and programmatic approaches;
- Strengthen the capacity of the UN system to monitor trends and ensure that appropriate and effective policies and strategies are implemented at the country level;
- Strengthen the capacity of national governments to develop comprehensive national strategies and implement effective HIV/AIDS activities at the country level;
- Promote broad-based political and social mobilization to prevent and respond to HIV/AIDS within countries, ensuring that national responses involve a wide range of sectors and institutions;
- Advocate greater political commitment in responding to the epidemic at the global and country levels, including the mobilization and allocation of adequate resources for HIV/AIDS-related activities.

Activities of UNAIDS are carried out at both the global level and country level (an approximately 40:60 ratio). UNAIDS works with national governments, intergovernmental organizations, non-governmental organizations, the private sector, groups of people living with HIV/AIDS, and the United Nations system organizations.

The HIV/AIDS epidemic continues to expand at the rate of about 8,500 new infections per day, with a particularly devastating effect in developing countries, where it is primarily a heterosexual disease. Consequences include overwhelming of health services, loss of skilled workers and managers, loss of farm production capacity, millions of orphaned children, and threats to stability in some countries. For the first time in the recording of statistics, life expectancy is falling and infant mortality is rising in the 15 most affected countries. These are the two most commonly accepted indicators of development.

The 1996-97 Budget

As of February 15, 1997, UNAIDS had received \$35,117,499 from the Eight, not including outstanding pledges. The total from all governments and co-sponsoring agencies is \$67,121,550. Together with carryover from the former WHO Global Program on AIDS and other miscellaneous income, this totals \$116,035,259 for the two year budget biennium. In the absence of the carryover funds from the WHO/GPA, UNAIDS would not have been able, based on received contributions and outstanding pledges to be received in 1997, to meet its \$120 million approved two-year budget.

Coordinated Appeal for Supplemental Activities

Co-sponsoring agencies must use this money for activities agreed upon in advance with UNAIDS and they must fit within UN-wide coordinated HIV/AIDS control plans. They cannot request funding for HIV/AIDS outside the coordinated appeal program. Thus far, \$1.8 million has been contributed to the supplemental appeal for \$18 million.

INTERNATIONAL AIDS VACCINE RESEARCH INITIATIVE

Objective:

A safe and effective AIDS vaccine is a global public health imperative. At the Denver Summit, the Eight should endorse an acceleration of research toward the development of an HIV/AIDS vaccine as a scientific and public health priority. There is an urgent need for high level political commitment to this initiative and for each of the Eight to provide, within their own countries, the investments necessary to energize scientific efforts in this area. Scientific collaboration and coordination can be enhanced through the NIH AIDS Vaccine Research Committee.

Key Points:

(1) The Director of the National Institutes of Health (NIH) will consult with his counterparts in the Eight prior to the Summit about this proposal.

- The purpose of this consultation would be to determine the areas where additional efforts would be most productive and where additional scientific collaboration and cooperation would benefit vaccine research.
- Recommendations resulting from this consultation would be available for consideration by the Eight at the Denver Summit.

(2) To provide continuity and to monitor scientific progress and activities, key scientists from the Eight and others that have made a significant investment in AIDS vaccine research should meet on an annual basis, in concert with the U.S. NIH AIDS Vaccine Research Committee.

- The primary role of this group will be to address the scientific issues related to the development of AIDS vaccine candidates for worldwide use.
- The group will discuss research progress, identify scientific gaps and opportunities, design collaborative programs to utilize the unique scientific and clinical resources of each participant, and share scientific information.

(3) As the appropriate opportunities arise, international cooperative activity can be mediated through the UNAIDS Vaccine Advisory Committee to assist in developing international sites for vaccine research and testing and to promote effective collaboration between the developed and developing world in this effort.

(4) A greater global investment in AIDS vaccine research, together with international collaborative efforts, promise to speed us toward the goal of developing a protective HIV vaccine.

Background:

More than 29 million men, women, and children around the world have been infected with HIV. More than 3 million of these infections occurred in just the past year, with nearly 95% in the poorest parts of the world. AIDS has brought about a significant decline in overall life expectancy in many African countries, threatening the economies of these already poor nations and robbing them of their workforce. Without an effective vaccine, AIDS will soon overtake tuberculosis and malaria as the leading infectious cause of death in the world. Even among the Eight, where anti-HIV therapies are available, complacency is not an option. HIV is capable of mutating and becoming resistant to therapies, and could well become even more dangerous. Only a truly effective preventive anti-HIV vaccine can limit and eventually eliminate the threat of AIDS.

Whereas formidable scientific obstacles have impeded the development of an HIV vaccine, new advances in immunology and recent dramatic progress in understanding how HIV causes infection, create an unprecedented opportunity. With vigorous scientific effort, HIV vaccine development should be within our grasp.

Ongoing International Collaboration

Cooperation among scientists, governments, non-governmental organizations, and international agencies can hasten the development of an effective AIDS vaccine for the benefit of all nations. Several of the Eight participate in active programs of international collaboration and cooperation, as do countries severely affected by HIV/AIDS. Many of the Eight have bilateral agreements that include AIDS research efforts, and many of our institutions and scientists have close informal working relationships.

HIV vaccine research is of major importance in the U.S. agreement with France (NIH-INSERM Biomedical Research Agreement) and in informal arrangements with scientific institutions in the U.K. and Canada. A number of other agreements emphasize cooperation in basic research areas that can lead to the development of new and novel approaches for the design of a preventive HIV vaccine. A U.S.-Indo Vaccine Action Program, for example, has been established under the auspices of the U.S.-India bilateral agreement that places a high priority on the inclusion of HIV vaccines under its development plans. Collaborative agreements regarding AIDS research also exist between other nations, such as Japan and France.

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The President's FY 1998 budget calls for \$150 million for HIV vaccine research, an increase of 33.6% over the FY 1996 appropriation. NIH has appointed distinguished scientists to an AIDS Vaccine Research Committee to provide new leadership to the NIH HIV/AIDS vaccine effort. The Committee is already engaged in international collaboration.

JOINT UNITED NATIONS PROGRAM ON HIV/AIDS (UNAIDS)

Objective:

The Eight should openly recognize the severity of HIV/AIDS globally and make a commitment to provide funding for UNAIDS, both core support and the global supplementary funding appeal.

Key Points:

(1) The Joint United Nations Program on HIV/AIDS (UNAIDS), which came into formal existence in January 1996, is the body within the United Nations system responsible for leading a global effort to expand the scale and quality of the response to HIV/AIDS.

- The principle behind the creation of UNAIDS was, and continues to be, that HIV/AIDS is not just a health issue, but rather an issue involving economics and development, education, and other sectors of society and government.
- The Eight were major advocates for the creation of UNAIDS.

(2) UNAIDS is an important example of UN reform in action.

- The first "virtual" UN organization, it provides centralized policy, international best practices, and advocacy.
- The co-sponsoring and other UN agencies develop and implement programs, providing synergy, policy coordination, and a reduction in administrative costs.

(3) UNAIDS' efforts to prevent and control HIV/AIDS remain woefully underfunded.

- The Eight have provided \$35 million for the 1996-97 biennium (\$18 million from the U.S.) toward the approved budget of \$120 million.
- Although UNAIDS will meet its budget from other donors and carry-over funds from the old WHO Global Program on AIDS, core funding for the 1998-99 biennium is a critical need.

(4) It is also important to increase funding for the "Coordinated Appeal for Supplemental Activities."

- This coordinated appeal is for \$18 million requested for (and by) the six co-sponsors for specific AIDS activities.
- This fund, and the activities, are coordinated by UNAIDS. It increases UNAIDS' credibility and enables UNAIDS to provide funds for country-level operational efforts.

Background:

UNAIDS is jointly sponsored by the World Health Organization, the United Nations Children's Fund, the UN Population Fund, UNESCO, the United Nations Development Program, and the World Bank, each of which provides some support to the organization.

Headquartered in Geneva, UNAIDS is headed by an Executive Director, Dr. Peter Piot (Belgium). Ambassador Sally Cowal, Director for External Relations, is the senior U.S. staff member.

The governing body of UNAIDS is called the Program Coordinating Board (PCB) and is currently chaired by Ambassador Sally Shelton-Colby, Assistant Administrator of USAID. Current members of the PCB are Algeria, Barbados, Bulgaria, China, Japan, Netherlands, South Africa, Sweden, United Kingdom, Congo, France, India, Pakistan, Paraguay, Russia, Uganda, and the United States. Chairmanship of the PCB passes from the United States to South Africa in April 1997. Representatives of five non-governmental organizations are also on the PCB.

The principal functions of UNAIDS are to:

- Provide global leadership in the response to HIV/AIDS;
- Achieve and promote global consensus on policy and programmatic approaches;
- Strengthen the capacity of the UN system to monitor trends and ensure that appropriate and effective policies and strategies are implemented at the country level;
- Strengthen the capacity of national governments to develop comprehensive national strategies and implement effective HIV/AIDS activities at the country level;
- Promote broad-based political and social mobilization to prevent and respond to HIV/AIDS within countries, ensuring that national responses involve a wide range of sectors and institutions;
- Advocate greater political commitment in responding to the epidemic at the global and country levels, including the mobilization and allocation of adequate resources for HIV/AIDS-related activities.

Activities of UNAIDS are carried out at both the global level and country level (an approximately 40:60 ratio). UNAIDS works with national governments, intergovernmental organizations, non-governmental organizations, the private sector, groups of people living with HIV/AIDS, and the United Nations system organizations.

The HIV/AIDS epidemic continues to expand at the rate of about 8,500 new infections per day, with a particularly devastating effect in developing countries, where it is primarily a heterosexual disease. Consequences include overwhelming of health services, loss of skilled workers and managers, loss of farm production capacity, millions of orphaned children, and threats to stability in some countries. For the first time in the recording of statistics, life expectancy is falling and infant mortality is rising in the 15 most affected countries. These are the two most commonly accepted indicators of development.

Current G-7/P-8 Support for UNAIDS:

As of February 15, 1997, UNAIDS has received from the Eight, for the 1996-97 biennium, the following:

Canada	\$ 2,564,635
France	2,330,097
Germany	2,337,506
Italy	198,020
Japan	2,650,000
UK	7,037,241
US	18,000,000
Russia	-0-
Total	\$35,117,499

In addition, there are outstanding pledges from Japan (\$1.8 million), U.K. (\$5.3 million), and Germany (\$1.5 million).

The total from all governments (including over \$6 million each from Sweden, the Netherlands and Denmark) and co-sponsoring agencies is \$67,121,550. Together with carryover from the former WHO Global Program on AIDS and other miscellaneous income, this totals \$116,035,259 for the two year budget biennium. In the absence of the carryover funds from the WHO/GPA, UNAIDS would not have been able, based on received contributions and outstanding pledges to be received in 1997, to meet its \$120 million approved two-year budget.

Coordinated Appeal for Supplemental Activities

Co-sponsoring agencies must use this money for activities agreed upon in advance with UNAIDS and they must fit within UN-wide coordinated HIV/AIDS control plans. They cannot request funding for HIV/AIDS outside the coordinated appeal program. Thus far, only \$1.8 million has been contributed to the supplemental appeal for \$18 million.

The G-7 countries are among the most likely candidates to be able to make substantial future contributions both to UNAIDS core funding and to special appeals. Considering the severity of the HIV/AIDS problem, the level of support from G-7 countries, with the exception of the United States and the United Kingdom, has been relatively modest.



April 16, 1997

Office of International Affairs
Washington, D.C. 20201MEMORANDUM FOR BILL ANTHOLISFROM : David Hohman 

SUBJECT: Funding for UNAIDS

I understand that at the Sherpa meeting earlier this month, some countries (UK and Japan) expressed the opinion that UNAIDS was not underfunded. I thought it would be helpful to address that misconception.

UNAIDS is entirely funded on a voluntary basis and operates on the basis of a budget approved by its Programme Coordinating Board (PCB). The only reason that UNAIDS met its 1996-97 budget of \$120 million (towards which the Eight contributed \$35 million) was because UNAIDS received approximately \$32 million in carry-over funds from the old WHO Global Program on AIDS. Those funds will not be available for the next biennium (also budgeted at \$120 million), as they must be put aside as part of the mandated "working capital fund." UNAIDS is, therefore, \$47 million short in its collections for the 1996-97 biennium.

Major concerns exist about the predictability and sustainability of funding for UNAIDS in view of:

- lack of equitable sharing of the UNAIDS budget by the Eight; while the US, UK, and Japan contribute the most, Canada, Germany, France and Italy are small donors.
- difficulty of planning and implementing activities because (i) uncertainty if approved budget will be fully underwritten until the third or fourth quarter of the year, when donors tend to make their contributions; (ii) some donors give priority to financing activities outside the approved budget; and (iii) unpredictable currency fluctuations.
- only 10% of the \$18 million Coordinated Appeal for Supplemental Activities has been contributed.

At its meeting this month, the PCB urged member states to reach a common agreement on ways to ensure predictability of funding. We believe that some of the Eight could increase their contributions to UNAIDS, particularly those that are contributing to development cooperation in areas very closely related to the work of UNAIDS (e.g., drug abuse and HIV/AIDS) or devoting considerable resources to regions where the HIV/AIDS epidemic is spreading rapidly (e.g., Eastern Europe).

FAX

TO: Ms. Sandy Thurman FAX: 202-619-5340
FROM: Mark King, AID Atlanta 404-872-0600 ext. 215
RE: AIDS Line Frequently Asked Questions
Safer Sex Curriculum

TOTAL PAGES:

NOTES:

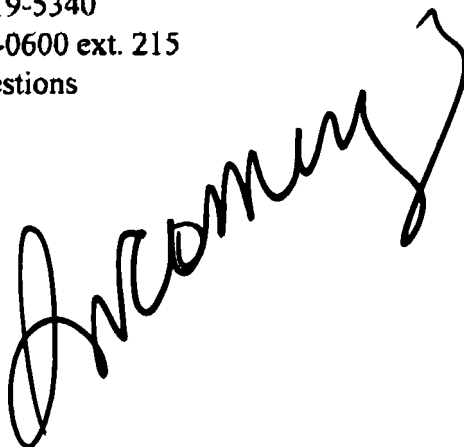
Sandy:

Hiya darlin'!

Attached are the items you requested.

For the "15 Frequently Asked Questions," I added brief notes on what I believe drives these questions or makes them come up again and again.

The curriculum for INDULGE is designed for gay men, but could be adapted. Depending on your needs, this may be far too explicit, but is worthy of a look. We can't locate the original on computer to print you out a fresh copy, so sorry about the scribbles on it!



**The 15 Most Frequently Asked Questions
at the Georgia AIDS Information Line**

1) Where can I get tested?

This calls increase dramatically when a celebrity or public figure announces they have AIDS.

2) Can you get AIDS from oral sex? From non-insertive sex?

The "mechanics" of HOW one transmits HIV (exchange of blood fluids) are still confusing to most people.

3) How soon after exposure can you get an accurate HIV test?

Many people want a test "the morning after."

4) How safe are condoms?

Most often when condoms "fail," they haven't been used correctly.

5) Can you get HIV from kissing?

Many questions are similar to this one: including getting it from touching, hugging or sleeping together in a non-sexual way.

6) What are protease inhibitors?

There is wild curiosity about "the cocktail," which many callers refer to as "the cure."

7) Are my children safe around someone with AIDS?

Sadly, the children referred to are often the patient's brothers and sisters.

8) If you have sex with someone who has the virus, do you automatically get it?

There is little distinction between "sex" and "safer sex."

9) Is it easier for a man to give it to a woman, or the other way around?

Again, the mechanics of HIV transmission are a mystery to most.

10) What are the early signs or symptoms of AIDS?

Callers often confuse the way a person "looks" with their HIV status.

11) I'm starting a relationship with someone who's HIV positive. How can I protect myself?

It is encouraging that, for many, life and relationships go on beyond AIDS.

12) Can I get HIV from eating at a restaurant?

Basic facts about HIV transmission are still unknown, and fear is a powerful thing.

13) I'm having trouble coping. Where can I get counseling?

The stigma and emotional pressure of living with HIV still takes an enormous toll.

14) My (friend) has just been diagnosed with HIV. How long will s/he live?

AIDS is still viewed as a virtual death sentence by many.

15) I think someone I work with has AIDS. How do I protect myself?

Workplace fears are a major new issue, especially with people with HIV remaining productive longer. Workplace education would dispel myths and prevent lost productivity.

“INDULGE!” Summary & Notes

In the interest of keeping “INDULGE!” to three hours, we now make Section III., “Transmission/ Sex Activities” more interactive by having participants list different sexual activities, which are written on a flip chart, discuss the body fluids involved with that activity, the point of entry into the partner during the activity, and determine their own level of acceptable risk. The risk of each activity is discussed including a condom and if the partners do not use one. The “Risk Identification” discussion is shortened as a result of this change in format.

Early in the session, right after the Ground Rules and Introductions, we added another activity, called the “Eroticism Discussion.” We have participants define the word “Erotic” by filling out a worksheet (included with the curriculum), then talk about what they find erotic. This discussion seems to work best when the participants are divided into groups of two for the beginning of the discussion, then return to the larger group to share the themes discussed in pairs.

In Section IV., a Strap-on demonstration model is not available, so the condom demonstration and discussion are slightly modified. The “Risk Identification” Section (VI) has been shortened because much of the point of it is covered in the new “Transmission/ Sex Activities” format. The “Negotiating” Section (VII) is a discussion of the participants’ responses to the question “How do you let your partner know that Safer Sex is what you want?” There are a list of points for the facilitator to use to lead the discussion. Regrettably, the question was deleted in this draft of the curriculum.

The “Eroticism Discussion,” the “Transmission/ Sex Activities,” and the “Erotic Stories” sections of the curriculum are consistently cited in evaluations as particularly valuable.

Eroticizing During Cards

INDULGE! WORKSHOP OUTLINE (10-95 REVISION)

As participants arrive have them fill out the demographics sheet and turn it in to you. Have the room set up with safe/erotic videos playing on a couple of screens and tables set up with various sexual items such as condom/lube, toys, porn, household sexual items, leather, etc. Allow participants to look at the items on the tables.

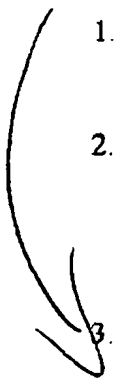
I. INTRODUCTION

5 minutes

A. Introduce host and facilitators.

B. Thank participants for attending.

C. Discuss purpose of INDULGE! workshop:

- 
1. increase knowledge about HIV infection, transmission, prevention, and risk reduction;
 2. assist in personal risk assessment and in making informed choices about sexual behaviors. Stress that we are not there to tell them what they can or cannot do, you are there to increase their knowledge so that they can make informed decisions;
 3. identify ways to eroticize protected sex, thereby making it a fun and acceptable alternative;
 4. explore your role and responsibilities in your community.

II. GROUND RULES (Be brief and informal)

5 minutes

A. Ask to make sure that everyone has signed the confidentiality sheet.

B. Establish guidelines for the party and explain the importance of each guideline.

- | | |
|-----------------------|---------------------|
| 1. confidentiality | 5. no wrong answers |
| 2. non-judgmental | 6. use imagination |
| 3. "I" statements | 7. anyone can pass |
| 4. speak as you would | |

III. TRANSMISSION / SEX ACTIVITIES

- 30 minutes
- A. Let the group know that we are going to go over some HIV basics, because knowledge and anxiety reduction are important when it comes to being able to eroticize sex.
 - B. Go over the body fluids which transmit HIV: **BLOOD, SEMEN, PRECUM, VAGINAL SECRETIONS, BREAST MILK**. Place visual aids on board as you go over them. Acknowledge the fact that other fluids can contain HIV, however they are not considered to contain large enough quantities of the virus to cause infection, they are only potentially infectious if blood is also present.
 - C. Using flip cards with various behaviors, ask participants to indicate possible HIV transmission methods. Ask the group to refer back to the bodily fluids when making their decisions. Also, have them indicate a way to make the activity safer. **EMPHASIZE THAT THERE ARE NO RIGHT OR WRONG ANSWERS. WHAT I CONSIDER SAFE, SOMEONE ELSE MAY NOT. IT IS IMPORTANT TO GET AWAY FROM "LABELING" ACTIVITIES SAFE OR UNSAFE AS MOST ACTIVITIES CAN BE DONE BOTH WAYS.**
 - D. When relevant, make sure they know the risks to both the insertive and receptive partners. If the individual does not provide you with a complete answer, tactfully throw the question out to the group. Don't give the answers unless it is absolutely necessary.
 - E. Draw an analogy with other activities which involve a certain amount of risk: hang gliding; driving a car; bungee jumping; climbing a ladder; walking around in a lightning storm; etc. Come up with your own examples, including humorous ones. The objective here is to get some perspective, and to emphasize personal choice.
 - F. Encourage the group to be willing to make **INFORMED** changes in their risk boundaries, based on increased knowledge and information from current research and studies.

IV. CONDOMS AND LUBRICANTS

- 15 minutes
- Ask how many in the group know all there is to know about condoms and lubricants. Pick a couple of volunteers to assist. Give a strap on dildo to one of the volunteers and ask the other to put the condom on the dildo correctly when we are ready for the condom demonstration.

- A. Ask the volunteers what you need to know about condoms and lubricant. Make sure that the following points are covered regarding condoms:
1. Latex, not animal membrane.
 2. Made in U.S.A. (or FDA approved)
 3. Expiration date.
 4. Different sizes, thickness, etc. Find one you with which you are comfortable.
 5. Keep them away from heat.
 6. Keep them handy (Where you have sex!)
- B. Make sure that the following items are covered during the condom demonstration:
1. Open them carefully.
 2. If no reservoir, make one.
 3. Pinch tip to keep out air bubbles.
 4. Roll back foreskin, if any, before putting on.
 5. Hold base of condom when you withdraw.
 6. Withdraw immediately after cumming.
 7. Use each condom only once.
 8. If you even **THINK** it may have broken, withdraw immediately.
 9. Place small amount of lube in tip of condom to increase sensitivity.
 10. **PRACTICE, PRACTICE, PRACTICE!!!!**
- C. Make the following points about lubricants:
1. Water based (not water soluble).
 2. **DO NOT USE OIL BASED LUBRICANTS.** (If you have the materials, blow up a condom and rub it with oil based lube and show the group how it pops.)
 - a) Petroleum jelly (vaseline)
 - b) Any kind of oil (baby, suntan, etc.)
 - c) Vegetable shortenings (Crisco)
 - d) Butter or Margarine
 - e) Whipped Cream
 - f) etc.
 3. Nonoxynol 9 - spermicide is backup protection only. Some people are allergic to it.
- D. Cover polyurethane condoms and their advantages and disadvantages.

- E. Discuss Latex Gloves / Finger Cots/Plastic Wrap/Dams

BREAK

10 minutes

Let the participants know what we will be covering after the break. There is a possibility that a participant may use this opportunity to leave. Do not confront the person. Try to keep yourself available for any questions a participant may want to ask in private.

V. SMALL GROUP - PARTICIPANT INTRODUCTIONS

10 minutes

- A. Break larger group up into smaller groups by having them count off 1,2,3,4 (# can vary due to group size) 1,2,3,4. Six to eight people in each group is ideal.
- B. In small group, pair participants up with someone they don't know; each one has one minute to introduce himself to his partner, then each participant introduces his partner to the group.

VI. RISK IDENTIFICATION (Still in small groups)

10-15

~~20~~ minutes

- A. Ask the participants to think about the following questions (it is VERY important for the facilitator to make this as non-threatening as possible. Be aware that there are going to be some people who will not be comfortable answering the questions):

Share own experiences

1. How many of you know exactly what your sexual limits are and will not go past them no matter who you are with?
2. How many of you sometimes find yourself doing things that you do not want to do?
3. How many of you sometimes put yourself at risk for being infected with HIV or other sexually transmitted diseases? Why do you think other STD's are included in this question?
4. How many of you know exactly what safer sex is?
5. How about oral sex?

Various agencies and groups have, based on the limited knowledge available, classified the risk associated with unprotected oral contact. For example, "minimal-to-low risk" (Canadian AIDS Society), "high-risk" (U.S. Centers for Disease Control), "possibly safe" (Columbus AIDS Task Force), "dangerous" (Charlottesville AIDS Task Force), "safe under certain conditions" (Buro GVO, the Netherlands), and "safe" (Queensland AIDS Council, Australia). It is understandable why there is so much uncertainty in the gay community over the risk of oral sex.

- B. Point out that feelings/guilt influence our behaviors, and that unacknowledged/suppressed negative feelings about safer sex can sabotage our ability to maintain safer behaviors.

VII. NEGOTIATING (Still in small groups)

How do you let your partner know that's where you're coming from

Emphasize the following:

10 minutes

- A. It is OK to say no and end a sexual encounter. If the person is very insistent, it might be best to call an end to things. What is the worst thing that can happen if you say no? What is the worst thing that can happen if you say yes?
- B. The importance of setting your sexual boundaries **prior** to a sexual encounter.
- C. Look for a "Win-Win" result. Try to find common sexual ground, so both parties can have a satisfying experience.
- D. ~~Recommend Slipping and Sliding for additional negotiating skills.~~

mod. GP - Sub. UP Negotiating

VIII. EROTICIZING

25 minutes

Procedural Note: It is important to make reinforcing statements (That sounds like fun. Oh, yea, goodness, etc.), perhaps camping it up a bit if it fits your personality. It is also important not to make judgements about the types of sex that people find interesting, as long as they're safe, and to make reconciling statements if a participant expresses displeasure with a particular sex act (If you're into it, why not? Sounds safe to me. I think that sounds kind of exciting.) Be daring, be audacious, spice things up. The whole point is to have fun.

- A. Have each group go around to the different tables (toys, leather, condoms, etc.) and pick up an item or two from each table.
- B. Have each group write an erotic story using the items from "A". The story should go from meeting/beginning thru climax. Everyone should have a chance to participate.
- C. Each group reads its story to the larger group.
- D. Emphasize that creativity and intimacy is important in making and keeping safer sex fun, exciting, and satisfying. Eroticism is in the mind, not the penis. Ask the participants what they would do to make their sex life more erotic if condoms were not an issue.

Go back to large group.

IX. TESTING

- 5 minutes Ask group if there are any questions concerning HIV testing. Let participants know that a list of test sites is available. Let participants know about AID Atlanta's testing program.

X. EXPERIENCE OF COMMUNITY

- 10 minutes A. Stress that each person has the power to protect himself and his partners, and to influence/support his friends in doing so. It is important for all of us to take personal responsibility for ourselves. However, there is also a shared responsibility for the health of our community. **THE HEALTH OF THE COMMUNITY AFFECTS ALL OF US.** We have the power to stop HIV transmission in our community.
- B. Make a strong plug for volunteering as a way of becoming involved in their community. Share your own experience and the rewards you have received.
- C. Review Slipping and Sliding program and urge participants to sign up.

XI. CLOSE

- 5 minutes A. Pass out evaluation sheet.
- B. Collect evaluation

BEFORE YOU LEAVE.....

Hang around for a few minutes looking approachable; someone may have a questions he wants to ask privately.

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4-21-1997 6:05PM FROM

CNN MID NEWS

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infection that could have been prevented by AZT or a similarly effective regimen—a total of 1,504 preventable deaths. Of these, 1,002 will occur in U.S.-funded studies and 502 will occur in those funded by foreign governments or the United Nations AIDS program. Even if only the placebo arms of the studies are considered, a total of 714 preventable HIV infections, 435 of them in U.S.-funded studies, will occur.

It is a violation of basic research ethics to assert that the failure to prevent HIV infection in these studies is somehow justified by the potential for preventing future HIV infections based on data that may be generated in this research. As the World Medical Association has declared: "Concern for the interests of the subject must always prevail over the interests of science and society."²³ In part, this ethical principle was enunciated to prevent the more powerful from using theoretical future gains to place the less powerful at risk in the present. Indeed, the very fact that the subjects of these studies are persons of color from impoverished, mostly post-colonial societies underscores the dangers of such rationalizations.

Clearly, any simpler or less expensive prophylactic regimen that was as effective and safe as that used in Protocol 076 would be rapidly adopted in the industrialized world and while it is true that many of the strategies being tested in these studies are less expensive than that used in Protocol 076, they may still be unaffordable in developing countries. There is, therefore, no guarantee that women and infants in developing countries will even benefit from any knowledge gained from this research. As a recent editorial entitled "Scientific Imperialism" in the *British Medical Journal* proclaimed: "If they won't benefit from the findings, poor people in the developing world shouldn't be used in research."²⁴

Defenders of these studies will no doubt argue that the subjects are being provided the "standard of care" practiced in these developing countries, which is to say regimens that have not been proved effective or no treatment at all. (Of course, this coerces potential subjects to enroll, as outside of the study they stand essentially no chance of obtaining proven effective prophylaxis.) Yet the standard of care in the U.S.—Protocol 076—can be delivered in the research setting in developing countries and is essentially being provided as one of the arms of the only developing country study here that is ethical: Harvard University's NIH-funded study of various regimens of AZT prophylaxis in Thailand. Researchers acquire greater ethical responsibilities when they enroll subjects in studies. As NIH Director Harold Varmus stated at a recent meeting regarding the Alaska needle exchange study, clinical trials funded by the NIH should comply with a higher ethical standard. Instead, many of these studies subscribe to a kind of lowest common denominator ethics in which the abominable state of health

²³ World Medical Association, *op. cit.*

²⁴ Wilmhurst P. Scientific Imperialism. *British Medical Journal* 1997;314:840-841.

care in developing countries is used to justify withholding life-saving interventions.

Incredibly, most of these studies have, to the best of our knowledge, passed ethical review by committees both in the developing country and in the West, providing further proof of the inadequacy of the current review system. We believe that the CDC-funded studies have passed review at the CDC itself, but do not know whether NIH's Office for Protection from Research Risks reviewed the NIH-funded studies. (The University researchers would also have been required to seek the formal approval of the Institutional Review Boards at their own institutions.) These events also demonstrate that the approval of a developing country ethics committee, while essential, is not sufficient to guarantee an ethical study. Developing country committee members, most of whom are likely to be researchers, are usually from social classes higher than the study subjects and may not be able to adequately reflect the subjects' interests. For developing country researchers, involvement in international studies offers obvious benefits in prestige and, perhaps, in salary.

It is true that providing AZT according to Protocol 076 or other similar regimens to all subjects could lower the number of new HIV infections to the point that it may be more difficult to statistically demonstrate differences between the study groups. Indeed, this is the crux of the researchers' conflict of interest: it is the potential for large numbers of infections among women denied AZT that makes the developing countries "preferable" as study sites to industrialized countries where AZT would have to be provided to all HIV-positive pregnant women. The solution to this conflict of interest is not to create a research double-standard; it is to spend the money for larger studies, perhaps at multiple sites in the industrialized or developing worlds, with appropriate informed consent. For example, one study arm could receive AZT and the other AZT and the experimental prophylactic regimen. With the public scrutiny that will accompany these studies, as well as the HIV vaccine studies that may follow, researchers cannot afford to be unethical.

The failure to provide effective prophylaxis to all women in these research studies can also not be explained by the cost of providing AZT in the research setting; after all, both the U.S. studies offer anti-HIV drugs to all subjects and seven of the studies outside the U.S. provide some form of AZT prophylaxis in some study treatment arms. The wholesale cost of the Protocol 076 regimen has been estimated at \$614²⁵ and \$895²⁶ per person. In the context of the hundreds of thousands, if not

²⁵ Gorsky RD, Farnham PG, Straus WL, et al. Preventing perinatal transmission of HIV — costs and effectiveness of a recommended intervention. *Public Health Reports* 1996;111:335-341.

²⁶ Mauskopf JA, Paul JE, Wichman DS, White AD, Tison HH. Economic impact of treatment of HIV-positive pregnant women and their newborns with zidovudine: implications for HIV screening. *Journal of the American Medical Association* 1996;278:132-138.

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4-21-1997 6:06PM FROM

CNN MED NEWS

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millions, of dollars being spent on these studies, this is a modest amount of money. In any event, the manufacturer of AZT has in the past customarily provided the medication for these trials free of charge.

Following World War II, the Nuremberg Code of research conduct was adopted.²⁷ In this 50th year since the commencement of the Nuremberg doctor trials, it is disheartening in the extreme that, at a minimum, four of the ten principles of the Code have been abrogated in this research. (We have not yet obtained the informed consent forms for these studies, and so it is conceivable that additional principles of the code have not been followed and that the studies are therefore even more unethical than we state here. However, no informed consent process can make ethical the withholding of effective prophylaxis.) The violated Nuremberg principles are:

Principle Two: "The experiment should be such as to yield fruitful results for the good of society, unprocurable by other methods or means of study, and not random and unnecessary in nature."

Principle Four: "The experiment should be so conducted as to avoid all unnecessary physical and mental suffering and injury."

Principle Five: "No experiment should be conducted where there is an *a priori* reason to believe that death or disabling injury will occur except, perhaps, in those experiments where the experimental physicians also serve as subjects."

Principle Seven: "Proper preparations should be made and adequate facilities provided to protect the experimental subject against even remote possibilities of injury, disability, or death."

Is it really your Department's position that these Principles apply to research conducted in the U.S., but that researchers using U.S. taxpayers' money are free to disregard them the moment they leave our shores?

²⁷ Trials of war criminals before the Nuremberg Military Tribunals. op. cit.

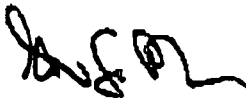
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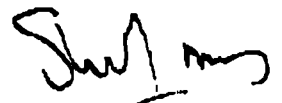
014
P. 14

We request that you immediately order the researchers in these studies to provide effective prophylaxis to all subjects in these studies and that you pressure the foreign governments who are also funding these studies to do likewise. We also request that you immediately ask the HHS Office of the Inspector General to launch an investigation into how these U.S.-funded studies received ethical approval and into possible violations of federal law. We are confident that you would not wish the reputation of your department to be stained with the blood of foreign infants.

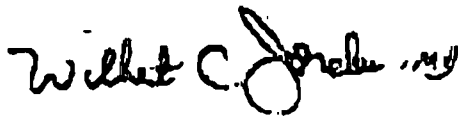
Sincerely,



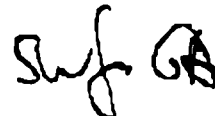
Peter Lurie, MD, MPH
Research Associate
Public Citizen's Health Research Group



Sidney M. Wolfe, MD
Director
Public Citizen's Health Research Group



Wilbert Jordan, MD, MPH
Director, Oasis Clinic and Aids Program
King-Drew Medical Center, Los Angeles
Chairman, Black Los Angeles
AIDS Consortium



George J. Annas, JD, MPH
Professor of Health Law
Health Law Department
Boston University
School of Public Health
Co-founder Global Lawyers and
Physicians: Working Together
for Human Rights



Michael A. Grodin, MD, FAAP
Professor of Medical Ethics
Health Law Department
Boston University
School of Public Health
Co-founder Global Lawyers and
Physicians: Working Together
for Human Rights



George Silver, MD
Emeritus Professor of Medicine
Yale University
School of Medicine

Office of
National AIDS Policy

Correspondence Routing Slip

Tracking Number: G3673

Date Rcvd: 04-21-97

From: Rosemary McKenzie
National Rural Health Association

Staff Action:

Reviewed By Sandy: _____ Reviewed By: _____

Assigned To: _____

RCVD: _____ DONE: _____

Recommendations/Instructions:

Info request

To Support Staff: _____

Date of Response: _____

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83



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Robert Tessen
Rural Health Clinics
Constituency Chair

April 16, 1997

Sandy Thurman
Director
National Office of AIDS Policy
808 17th Street, N.W., 8th Floor
Washington, DC 20006

Dear Ms. Thurman:

We are pleased to confirm your participation in the "Southeastern Conference on Rural HIV/AIDS: Issues in Prevention and Treatment" scheduled for August 14-15, 1997 in Atlanta, Georgia. The conference will be held at the Hyatt Regency Atlanta, 265 Peachtree Street, N.E., Atlanta, GA 30303, 404-577-1234.

You are scheduled to give opening remarks on Thursday, August 14, 1997 from 1:30 p.m. - 2:00 p.m. and participate in the Town Hall Meeting Thursday, August 14, 1997 from 7:00 p.m. - 9:00 p.m. Other participants in the Town Hall Meeting will be Joseph O'Neill, M.D., M.S., M.P.H., Acting Director, Bureau of Health Resources Development/HRSA and R. Scott Hitt, M.D., Chairman, Presidential Advisory Council on HIV/AIDS. Please send in advance any background papers or articles relative to your presentation for participants. We will need the material no later than **July 15, 1997**.

Enclosed is a speaker's packet which requests information that is needed to complete the final program. Please return the forms by **July 1, 1997**.

There will be display tables for literature and resource materials, so feel free to bring anything you wish displayed. We are looking forward to having you present at this conference. If you have any questions, feel free to contact me.

Sincerely,


Rosemary McKenzie
Program Director

RM/s

Enclosures

Donna M. Williams
Executive
Vice President

NATIONAL OFFICE
One West Armour Boulevard, Suite 301
Kansas City, Missouri 64111
Telephone (816) 756-3140
Fax (816) 756-3144
E-mail: mail@nrharural.org

Internet:
<http://www.NRHArural.org>

WASHINGTON, D.C., OFFICE
1320 19th Street, N.W., Suite 350
Washington, D.C. 20036-1610
Telephone (202) 232-6200
Fax (202) 232-1133
E-mail: dc@nrharural.org

NATIONAL RURAL HEALTH ASSOCIATION

"Southeastern Conference on Rural HIV/AIDS: Issues in Prevention and Treatment"

August 14-15, 1997

Atlanta, Georgia

SPEAKER'S PACKET

Instructions: The information requested in this packet will be used to 1) develop the workshop final program; and 2) facilitate speaker requirements for individual presentations, i.e., audio visual needs, release forms, etc.

Please complete all forms and return **by July 1, 1997**. This information is crucial to the development of the final conference program. Thank you.

Return forms to:
Rosemary McKenzie
Program Director
National Rural Health Association
One West Armour Boulevard, Ste. 301
Kansas City, Missouri 64111
816/756-3140
816-756-3144 (FAX)

NATIONAL RURAL HEALTH ASSOCIATION

Release Forms

Part I - Policy Statement on Audio Taping

The National Rural Health Association reserves the right to tape all programs presented as part of its Southeastern Conference on HIV/AIDS: Issues in Prevention and Treatment, August 14-15, 1997 in Atlanta, Georgia, and to offer such tapes for sale, on site, in cassette form to NRHA members and friends.

Taping in no way prohibits speaker from using their material in another manner, e.g., publication.

I understand the intent of the NRHA in taping my presentation and offering it for sale. This in no way prohibits me from using my own material in any manner I so desire.

(Signature)

(Name - please print or type)

(Date)

Part II - Publicity Clearance

I hereby authorize the National Rural Health Association and/or any publication, periodical, television or radio program, station or network that has been cleared and approved by the National Rural Health Association to take and use my photograph and/or interview in any manner deemed appropriate.

I hereby surrender and waive all claims against NRHA and against any such cleared and approved publication, periodical, program, station or network for using my photograph and/or interview.

(Signature)

Part III - Permission to Print

Permission is granted, royalty free, to the National Rural Health Association to reproduce for sale, separately or as a part of a booklet, edited, or verbatim, the presentation delivered by me at the Southeastern Conference on Rural HIV/AIDS: Issues in Prevention and Treatment, August 14-15, 1997.

Permission to print this address has not been previously granted to any other person, firm, or corporation.

I understand that if NRHA decides to publish my manuscript, I will be responsible for obtaining permission to use excerpts from other published material quoted in my manuscript.

I confirm that with the exception of those cited materials, I understand that NRHA will notify me in advance whether or not it intends to publish my presentation.

(Signature)

NATIONAL RURAL HEALTH ASSOCIATION

Request For Audio-Visual Equipment

(Please Type)

NAME: _____

ADDRESS: _____

CITY: _____ STATE: ____ ZIP: _____

TELEPHONE: _____

SESSION TITLE: _____

DATE: _____ TIME: _____

I will need the following equipment for my presentation:

____ 35mm slide projector ____ Other (please list)

____ 35mm film strip projector

____ Overhead projector (for use
with large transparencies)

____ Cassette tape player

____ Easel/flip chart

____ Video Cassette Player with Monitor: Type _____ Size _____

Please remember that transparencies should be large enough to be read clearly by all session attendees. Flip charts and blackboards should only be used in small groups.

Note: Due to the increase in audio-visual equipment rental, we encourage you to choose your equipment from the above options. Please contact us if you require equipment not listed.

For Office Use Only:

Day:

Time:

Room:

Office of
National AIDS Policy

Correspondence Routing Slip

Tracking Number: G3672

Date Rcvd: 04-21-97

From: Donna M. Williams
National Rural Health Association

Staff Action:

Reviewed By Sandy: _____ Reviewed By: _____

Assigned To: _____

RCVD: _____ DONE: _____

Recommendations/Instructions:

8/97 Total Allerton
G

To Support Staff: _____

Date of Response: _____



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Constituency Chair

James Norton
Research and
Education
Constituency Chair

Bonnie Post
Community-operated
Practices
Constituency Chair

Thomas Robertson
Frontier Constituency
Chair

Robert Tessen
Rural Health Clinics
Constituency Chair

April 16, 1997

Sandy Thurman

Director

National Office of AIDS Policy

808 17th Street, N.W., 8th Floor

Washington, DC 20006

Dear Ms. Thurman:

The National Rural Health Association (NRHA), would like to thank you for agreeing to participate in the Southeastern Conference on Rural HIV/AIDS: Issues in Prevention and Treatment, scheduled for August 14-15, 1997 in Atlanta, Georgia. The conference, funded by the Office of Rural Health Policy/HRSA and the Ryan White CARE Act Programs/HRSA, will highlight effective strategies for preventing and managing HIV infection in rural areas of the Southeastern United States.

You are invited to give opening comments on Thursday, August 14 from 1:30 p.m. - 2:00 p.m., along with Claude Earl Fox, M.D., Acting Administrator/HRSA. We would also like your participation in the Town Hall Meeting, scheduled for Thursday, May 14, 1997 from 7:00 p.m. - 9:00 p.m. Other participants in the Town Hall Meeting will include Joseph O'Neill, M.D., Acting Director, Bureau of Health Resources and Development/HRSA and R. Scott Hitt, M.D., Chair, Presidential Advisory Council on HIV/AIDS.

We look forward to your participation in your new role as Director of the National Office of AIDS Policy, and congratulate you on this appointment.

If you have any questions, please do not hesitate to contact me.

Sincerely,

Donna M. Williams
Executive Vice President

DMW:rm

cc: Daniel Montoya

Donna M. Williams
Executive
Vice President

NATIONAL OFFICE

One West Armour Boulevard, Suite 301
Kansas City, Missouri 64111
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Internet:
<http://www.NRHArural.org>

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E-mail: dc@nrharural.org



THE NEW YORK ACADEMY OF MEDICINE

TO ENHANCE THE HEALTH OF THE PUBLIC

OFFICE FOR SPECIAL
POPULATION PROJECTS

April 10, 1997

Ms. Sandy Thurman
AIDS Policy Director
National AIDS Program Office
750 Seventeenth Street, NW Suite 1060
Washington, D.C. 20503

Dear Ms. Thurman:

I am writing to you on behalf of the Council of AIDS Program Directors, a group comprised of the medical directors of Designated AIDS Centers in New York State, to invite you to speak to the Council at one of our upcoming meetings.

The Council, which was instituted by Dr. David Rogers and is currently chaired by Drs. Jonathan Jacobs of the New York Hospital Center for Special Studies, Thomas Morris of Columbia Presbyterian Medical School and Victoria Sharp of the Beth Israel Medical Center, meets four times each year. I would like to know if you could join us on either May 29, 1997 or September 11, 1997 to discuss your views and plans as the national AIDS policy director. Your thoughts on access to care and costs of care are also of interest. You should be prepared to speak approximately 45 minutes which would allow substantial time for questions and answers. These are highly engaged and articulate clinicians who would love to have a chance to share their thinking with you.

Meetings are scheduled at 9:00 am and conclude at 11:00 am and are generally attended by 20 - 30 clinicians currently engaged in HIV care in New York. The meetings are held at the New York Academy of Medicine which is located at 1216 Fifth Avenue. I can provide reimbursement for hotel accommodations on the evening preceding the meeting and travel expenses.

1216 FIFTH AVENUE NEW YORK NEW YORK 10029-5293

Office of
National AIDS Policy

Correspondence Routing Slip

Tracking Number: G3677

Date Rcvd: 04-23-97

From: J. BRIAN ATWOOD

USAID - US AGENCY FOR INTERNATIONAL DEVEL.

Staff Action:

Reviewed By Sandy: _____ Reviewed By: _____

Assigned To: _____

RCVD: _____ DONE: _____

Recommendations/Instructions:

USMO meeting request

To Support Staff: _____

Date of Response: _____

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U.S. AGENCY FOR
INTERNATIONAL
DEVELOPMENT

April 12, 1997

The Administrator

Ms. Sandra Thurman
Director
Office of National AIDS Policy
750 17th Street, N.W.
Washington, DC 20503

Dear Ms. Thurman:

My congratulations on your appointment to head the President's Office on AIDS Policy. I hope we can continue to build on our excellent working relations.

USAID is committed to remaining the world's leader in international efforts to combat HIV/AIDS. We are the largest bilateral donor in this area and have been instrumental in establishing UNAIDS. In fact, our Assistant Administrator for Global Programs, Ambassador Sally Shelton-Colby, has just completed her term as the first chair of the Program Coordinating Board (PCB) for UNAIDS. Our field projects also serve as a model for other donors.

Over the past few years we have worked very closely with the White House Office on AIDS Policy. We have included the Office in all of our meetings with groups working on HIV/AIDS issues. We have directly provided staff support to the Office and sought the advice and assistance of the White House in the design and development of our international HIV/AIDS policies and programs.

I would very much like to meet with you at your earliest convenience to discuss how we might continue to work together and will be contacting your office in the very near future.

Sincerely,

J. Brian Atwood

Ms. Sandy Thurman
Page 2

I know you will be overwhelmed with requests to speak but I sincerely hope you will make a visit to New York a priority in the near future. Please call me at 212/822-7266 to let me know of your interest and availability. I do look forward to hearing from you and hope to meet you in the near future.

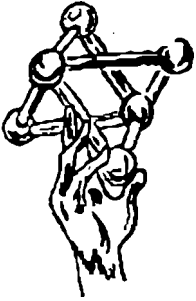
Thank you.

Sincerely,

A handwritten signature in cursive script that reads "Ellen R. Parish".

Ellen R. Parish
Health Policy Specialist

cc: A.Fleischman, MD
J. Jacobs, MD
T. Morris, MD
V. Sharp, MD
G. Stein, MSW, JD



Build-the-Monument Foundation, Inc.

Ms. Sandy Thurman
Director of AIDS Policy

April 10, 1997

Dear Ms. Thurman,

Congratulations on your appointment as the President's Director of AIDS Policy!

We are familiar with your work in Atlanta and wholeheartedly endorse your appointment. Your determination and courageous attitude are sorely needed in National AIDS Community.

We wish you the greatest success in your newest challenge and look forward to working with you in the future.

Be Well,

A stylized, handwritten signature in black ink, appearing to read 'Tee Browne'.

Tee Browne
President

Rich Needle -
Substance abuse staff

Extract from Nancy Ann
prevention
substance abuse

HUD ~~files~~ office -

- ★ Need Admin person -
Can't do admin with Agency Reps -
- ★ Need Communications person -

WH -

Nelson Cunningham, admin office (Interdepartmental task force)

- ★ Get hardpass ASAP from Ashley

NORA Executive

Sylvia Matthews
- Andy King

UN AIDS - Sally Shelton (USAID)
- Duff Gillespie

Nancy Ann Minn (OMB)

Policy
Special
Project
★ Microbicides -

Women -

Drugs - (5090 new infections)

Paul - 708 - 1939 4619

Mark/Going - 11:30 A/C, 3000 reception

April 8, 1997

Susan Libman
201 Centennial Hall
4400 Massachusetts Ave, NW
Washington, DC 20016

Sandra Thurman
National AIDS Policy Office
750 17th Street, NW
Washington, DC 20503

Dear Sandy,

Hi. I saw you on CNN last night...CONGRATULATIONS!! I'm not sure if you are going to remember me, but I worked in the Ticketing office at PIC with you. I was Kim Cubine's intern from the campaign and a ticketing assistant at the Inaugural. Generally, I kept those notebooks of Ticket Request forms organized and answered Jason Bovis's phone when he was busy.

Anyhow, I am graduating next month from American University with a degree in Journalism, and if you have any positions open on your staff, I would love to work with you again. While communications in my niche, working at the campaign and PIC really allowed the politics bug to bite me, and I am willing to work in any capacity. I did not know much about politics or public policy before I started working at Clinton/Gore GELAC, and I think I learned more through that internship than I could have learned in any course I could have taken in college. The whole political realm fascinated me.

Please feel free to call me at 202/885-6662 if you feel there may be an opening in your office. Even though my resume says I am looking for a position with editing or desktop publishing, I am willing to handle other responsibilities. The phone number will be valid until mid-May.

Thank you, Sandy. Congratulations again, and good luck in your new position.

Sincerely,

A handwritten signature in cursive script that reads "Susan Libman".

Susan Libman

P.S. I took a picture of you and Kim at the Ticketing Staff/Spaghetti Garden dinner. I believe Kim said she was going to make you a copy before PIC ended. Let me know if she didn't, and I will send one to you. It's a cute photo.

4400 MASS AVE., NW #201CEN • WASHINGTON, DC 20016

T: (202)885-6662 F: (202)885-1421

SL6317A@AMERICAN.EDU

Summary:

Looking for a position in communications to utilize desktop publishing skills. Have a love for travel - visited 14 countries. Expertise in IBM and Mac platforms, Windows 3.0/3.1, MS Word, Word Perfect, MS Publisher, Adobe PageMaker, Netscape Navigator, Quark Xpress (Mac only), Omnipage, Adobe Photoshop, scanning equipment (Mac only). Working knowledge of Windows '95, MS Excel, Fontographer

Education:

Bachelor of Arts in Journalism

The American University,

School of Communication

Projected: May 1997

Semester at Sea

University of Pittsburgh

Study Abroad Program

Spring 1996

Work Experience:

•Clinton/Gore '96, Inc. and the 1997 Presidential Inaugural Committee

Finance Department Intern (September 1996 - November 1996)

Acted as liaison between donors and Direct Mail/GELAC department

Responsible for "turning-around" over \$40,000 in checks

Ticketing Assistant (November 1996-January 1997)

Worked in all aspects of ticket sales, distribution, customer service

•Marriott Dining Services

Catering Associate (June 1994 - January 1996, June 1996 - Present)

Marketing Associate (October 1995 - January 1996)

Cashier (June 1996 - Present)

•META, Inc.

A government contracting company that focuses on environmental and protective services.

METALink Managing Editor (April 1995 - September 1995)

Wrote, designed and produced internal newsletter with 250 circulation

Extra-Curricular Experience:

•*The Talon*

The Undergraduate Yearbook of the American University

Managing Editor of Print Production (June 1996 - Present)

Develop yearbook design; assist in photo selection and story editing; manage production staff

•*The Eagle*

The Undergraduate Student Newspaper of the American University

Living Layout Editor (March 1995 - January 1996)

Designed and produced weekly Living (Style) section

Staff Writer (November 1993 - Present)

Honors and Activities:

•Named to Dean's List (Fall 1995 and Fall 1996 semesters)

•Society of Professional Journalists, AU Chapter; member since 1995

Chapter President (May 1995 - October 1995)

•Office of Student Services/New Student Programs

Orientation Assistant (Summers 1994-1996)

•American University Residence Hall Association

National Residence Hall Honorary; member since 1996

Centennial Hall Social Director (August 1995 - December 1995)

Living Learning Center Executive Board Member (September 1993 - May 1995)

REFERENCES AVAILABLE UPON REQUEST

SUSAN LIBMAN

TONIO BURGOS & ASSOCIATES INC.

April 8, 1997

Tonio Burgos
President

909 Third Avenue
17th Floor
New York, NY 10022
Tel. 212-826-2000
Fax 212-644-7485

Sandy Thurman
Whitehouse Aids Policy Director
Director 750
750 17th Street, NW - Ste 600
Washington, DC 20410

Dear Sandy,

I once again, want to congratulate you on your appointment by the President as Director of the Whitehouse Office on Aids Policy. Let me join our colleagues in pledging to you my full support.

If there is anything I can do to help in New York, New Jersey, Florida or Puerto Rico please let me know.

Hope to see you soon.

Sincerely,



Tonio Burgos

William Waybourn
President



1875 Connecticut Ave., N.W., Suite 640
Washington, DC 20009
(202)986-3060 Fax: (202)667-0902

April 7, 1997

The Honorable Sandy Thurman
Director, Office of National AIDS Policy
750 Seventeenth Street, Northwest
Suite 600
Washington, DC 20503

Dear Sandy:

Congratulations on your appointment to the position of Director of the Office of National AIDS Policy. There is no one more suited for the position, and I am excited to see the results of your work. Your dedication and work history demonstrate what an asset you will be to this administration as well as the ongoing battle against HIV/AIDS.

I am always happy to assist you in whatever way possible. Please do not hesitate to contact me at 202.986.3060 should you need anything.

I wish you all of the best in your new endeavor.

Sincerely,

William Waybourn
President



William Waybourn
President

1875 Connecticut Ave., N.W., Suite 640
Washington, DC 20009
(202) 986-3060
Fax: (202) 667-0902
E-mail: waybourn@widmeyer.com

JACK P. TURNER
1445 RESURGENS PLAZA
ATLANTA, GEORGIA 30326

April 18, 1997

Dear Sandy:

Frances and I are proud of you. The President did a good day's work when he appointed you Director of the National AIDS Policy Office. I know that your mother and dad would be greatly pleased in the way that you have served our community, state and country.

We are also, of course, very pleased that you involved in Democratic causes!

Frances works in the office on Tuesday, Wednesday and Friday afternoons. We hope that you will come see us when you are in town.

Your friend,

A handwritten signature in dark ink, appearing to be "J.P. Turner", enclosed within a large, loopy circular flourish.



DEPARTMENT OF HEALTH & HUMAN SERVICES

Office of the Secretary

Office of International Affairs
Washington, D.C. 20201

April 25, 1997

Handwritten signature/initials

MEMORANDUM FOR:

Laura Efros, OSTP - 456-6028
Robin Ritterhoff, Treasury - 622-2023
Peter Chase, State - 647-9763
Nancy Carter-Foster, State - 736-7336
→ Sandy Thurman, Office of National AIDS Policy - 632-1096
Paul DeLay, AID - 703/875-4686
Jo Ivey Boufford, HHS

FROM: David Hohman

Handwritten signature of David Hohman

SUBJECT: Denver Summit Communiqué

Attached for your review and clearance is draft communiqué language for the Denver Summit on HIV/AIDS - the vaccine initiative and UNAIDS. It is based on the material prepared for the last Sherpa meeting.

I will be grateful if you will give me your comments/clearance by noon on Monday, April 28. If I do not hear from you, I will assume that you clear this language.

My telephone number is 202/690-6174 and my fax number is 202/690-7127.

Attachments

1. International AIDS Vaccine Research Initiative
2. Joint United Nations Program on HIV/AIDS (UNAIDS)

04/23/87 10:21 202 080 7127 HHS INLE AFFAIRS 0001

Draft Denver Summit Communiqué

International AIDS Vaccine Research Initiative

AIDS poses one of the greatest threats to the health and security of nations and their citizens. At the last Summit in Lyon, our governments agreed on the importance of taking action to address the growing threat of emerging infectious diseases, including HIV/AIDS. At this Summit we have agreed that the development of a safe and effective vaccine against AIDS is an urgent global public health imperative. We are committed to providing, in our own countries, the investments necessary to accelerate AIDS vaccine research. We also pledge to work together to enhance international scientific cooperation and collaboration in this global initiative, and to work with the Joint United Nations Program on HIV/AIDS (UNAIDS) to address the legal and ethical issues related to vaccine testing. Cooperation among scientists, governments, and international agencies is critical to this new global initiative. Scientific progress in the development of an AIDS vaccine will provide important advances that will aid in the development of vaccines for other infectious diseases that continue to threaten the world's population. We call on other states to join us in this important endeavor to enhance international cooperation and increase the worldwide investment in AIDS vaccine research for the benefit of all nations. Only a truly effective preventive AIDS vaccine can limit and eventually eliminate the threat of AIDS and its devastating human, economic, and social consequences.

Draft Denver Summit Communiqué

Joint United Nations Program on HIV/AIDS (UNAIDS)

Recognizing that HIV/AIDS is not just a health issue, but rather one that involves economics and development, education, and other sectors of society, our governments were major advocates for the creation of the Joint United Nations Program on HIV/AIDS (UNAIDS). If UNAIDS is to fulfill its mandate, it must have the resources required to lead a global effort to expand the scale and quality of the response to HIV/AIDS. We reaffirm our commitment to provide funding for UNAIDS, and call on other states to join us in supporting this vital organization.



HIV Neurobehavioral Research Center

2760 5th Ave, Suite 200
San Diego, CA 92103
(619) 543-5000

April 9, 1997

To: Ms. Sandy Thurman
Director of National AIDS Policy

From: Andrew M. Mattison, Ph.D.
Associate Clinical Professor
Departments of Psychiatry and
Family & Preventive Medicine

Earlier today my dear friend of over 20 years, Dr. Steve Morin, urged me to write to invite you to be the closing plenary speaker of our 4th Western Regional Conference on **HIV, AIDS & Women** which will convene in San Diego September 25 - 28th, 1997. The purpose of the conference is twofold: 1) to assist medical professionals, service providers, HIV infected women, and other affected individuals in meeting the challenges of HIV/AIDS and 2) to offer HIV positive women an opportunity to develop and enhance their sense of self-empowerment, coping skills and other critical life management skills. Partial funding for the conference comes from the CDC.

The closing plenary session is on Sunday morning September 28th. The conference attendees (we are expecting approximately 500 persons) will be hearing about recent advances in diagnosis, and treatment of HIV infections in women, particularly the protease inhibitors, antiviral therapy in pregnant women and children. We would like the closing plenary to reflect the future as well as hearing of your public policy goals. Also, what you think various constituencies in San Diego (patients, providers, and community activists) can do to be more effective in interacting with the political process to help you achieve these goals.

Faculty at the University of California, San Diego, provide national leadership in AIDS scientific policy in such areas as molecular virology (Flossie Wong-Staal, Ph.D.), clinical therapeutics (Douglas Richman, M.D.), and pediatrics (Stephen Spector, M.D.). Several of us here at the HIV Neurobehavioral Research Center (HNRC) have served on several advisory panels such as the December 1995 White House Conference on HIV and AIDS (Igor Grant, M.D.) and on our local Congressman Brian Bilbray's AIDS Advisory Board (Igor Grant, M.D., J. Allen McCutchan, M.D., Andrew Mattison, Ph.D.).

We do hope you will seriously consider this invitation. If so, I would be delighted in organizing a community forum, possibly on Friday, September 26th, in which we would invite San Diegans to a town hall format in which you might make some comments and respond to questions. This program might be followed by a brief reception.

I do realize that you might have restrictions on receiving funding. However, we are able to offer RT airfare (economy), hotel accommodations, and a \$1,000.00 honorarium.

On behalf of all of us at the HNRC, I want to wish you very well on your new endeavor as our country's new Director of National AIDS policy.

April 6, 1997

To: Bruce Reed, Assistant to the President for Domestic Policy
456-2878 facsimile number
456-6515 telephone number
3 pages

From: R. Scott Hitt, Chair, Presidential Advisory Council on HIV and AIDS
(202) 862-1600 Madison Hotel

Re: Meeting with the Council on Monday, April 7, 1997 at 10:15am

Below are some statements and questions that we would like to address during your meeting with the Council.

The Council would like to encourage you to make sure that separate announcements be held regarding the proposed standards of HIV/AIDS care and vaccine research.

The Council understands that you have been very instrumental in working to enhance the Office of National AIDS Policy. We would like to emphasize the importance of several items regarding that Office:

1. The title for the director of ONAP should be Special Assistant to the President;
2. The Special Assistant to the President should have an office in the Old Executive Office Building and ample office space be provided for an increased staff.
3. The Office should be sufficiently staffed (including naming of Dr. Eric Goosby as Deputy); and
4. Continue to improve the coordination between the Office of National AIDS Policy and HHS.

Prison Issues:

What specific steps can be taken by the President or on his behalf by you to assure that caregivers in correctional sites are adequately trained and the full range of pharmaceuticals associated with HIV/AIDS management be available?

Discrimination Issues:

What specific steps can be taken by the President or on his behalf by you to resolve discrimination issues resulting from mandatory HIV testing policies of certain federal agencies?

Facsimile Transmittal Sheet



NAPWA

National Association of People With AIDS

DATE: April 10

TO: Sandy Thurman

FAX#: 632.1096

FROM: A. Cornelius Baker

OF PAGES (including Cover):

MEMO: I wanted to make you aware of correspondence sent to the White House earlier this year regarding the Tuskegee experiment. Additionally, as a consultant to the CDC "syphilis in the south" panel (and obviously as a black man) this issue has been a longstanding concern of mine. NAPWA has worked with Congressman Stokes and Bill White in Domestic Policy on this issue. Any additional help you can give to getting the individuals I sent to Ferdette invited to the ceremony would be appreciated. Finally, I'd like to talk with you about Sandy McD. when you have a moment.

**Congress of the United States
House of Representatives
Washington, DC 20515**

February 7, 1997

**The Honorable William Jefferson Clinton
President of the United States
The White House
1600 Pennsylvania Avenue, N.W.
Washington, D.C. 20500**

Dear Mr. President:

We are writing to you, on behalf of the Congressional Black Caucus, to request that you issue a formal apology, on behalf of the United States Government, with regard to the Tuskegee Syphilis Study. The national observance of Black History Month is a most appropriate time to issue such a long overdue apology to participants of that study, their families, and the African American community.

As you may know, there are five remaining survivors of that travesty. We strongly believe that it is absolutely imperative that these brave and dedicated men be recognized for the tremendous hurt, pain, and lifelong suffering inflicted upon them. Acknowledging these five men, would not only address the immediacy of the Tuskegee legacy for the living, it would also help the nation reclaim the dignity of those men who are no longer alive.

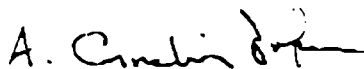
The painful legacy of the Tuskegee Syphilis Study continues to plague the African American community. It is most apparent in the AIDS epidemic, the syphilis epidemic in the southeastern United States, in minority populations' delay in seeking health care services, and in their fear of participating in lifesaving clinical trials. Almost 60 years after the study began, distrust and suspicion remain. That legacy dramatically hampers efforts to improve the health of African Americans and other minorities.

As we are sure you understand, there can be no justice and no faith can be regained in this nation's public health system until all those Black men, who were subjected to the Tuskegee experiment,

care system.

As a black man living with HIV infection, grateful for the vision you bring to our country as you enter your second term, committed to leading all of our people to the next century with a greater sense of freedom and justice, I hope that you will seize this historic moment to eradicate this vestige from our past.

Sincerely yours,

A handwritten signature in black ink, appearing to read "A. Cornelius Baker". The signature is fluid and cursive, with a long horizontal stroke at the end.

A. Cornelius Baker
Executive Director

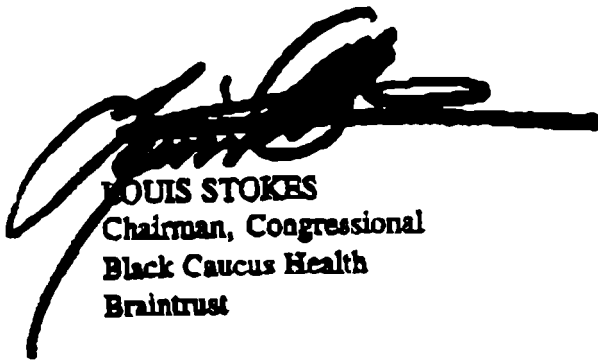
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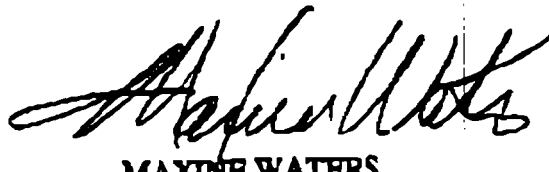
The Honorable William Jefferson Clinton
February 7, 1997
Page 2

have had their humanity recognized, validated, and restored. Now is the time to bring this sad chapter, in our nation's history, to an end by issuing a formal apology.

Sincerely,



LOUIS STOKES
Chairman, Congressional
Black Caucus Health
Braintrust



MAXINE WATERS
Chairwoman, Congressional
Black Caucus

cc: Secretary, DHHS
Director, CDC

LS/fw

8



For Immediate Release
February 11, 1997

Contact: A. Cornelius Baker
202.898.0414

NATIONAL COALITION CALLS FOR TUSKEGEE RECONCILIATION

Legacy of Study Hurts AIDS Prevention Efforts

1413 K Street, NW
Washington, DC
20005-3405
tel (202) 898-0414
fax (202) 898-0436
NAPWA FAX
(202) 789-2222
E-mail address:
napwa@thecure.org
Home page address:
<http://www.thecure.org>

Washington, DC - A national coalition of social welfare and AIDS service organizations, led by the National Association of People with AIDS (NAPWA), has called on President Clinton to end the government's painful silence on the Tuskegee Syphilis Study. The group is seeking an official apology for the inaction of public health officials during the course of the experiment.

"The truth is too many Americans still believe that public health officials are out to destroy them," said A. Cornelius Baker, Executive Director of the National Association of People with AIDS (NAPWA). "This belief has led to poor health conditions and rampant disease in communities who feel alienated from our society."

The Tuskegee study of untreated syphilis is reported to have been the longest nontherapeutic experiment on humans in medical history. The study in which black male participants were not educated or treated adequately for their disease was conducted from 1932 until 1972.

"We need to close the book on this sad chapter of American history so that we may better serve the public health," stated Mike Shriver, NAPWA's Director of Public Policy. "The silence of our nation's leaders gives false rise to conspiracy theories and grants justification for distrust of our health care system."

The campaign to reconcile the Tuskegee legacy has been a long term initiative of NAPWA. Over 100 organizations have joined this effort by signing a joint letter to President Clinton.

* * *

The National Association of People with AIDS speaks for people living with HIV infection and guides the nation toward a moral agenda to save lives, to support research for a cure, and to end human suffering.

Letter follows.

(Revised) February 10, 1997

The President
The White House
Washington, DC 20500

Dear Mr. President:

The Tuskegee study of untreated syphilis was the longest nontherapeutic experiment on human beings in medical history. In this study, public health officials failed to educate the black male participants or treat them adequately for their disease. As the February observance of Black History Month gets underway, we are writing in hopes that you will use your leadership to bring this sad chapter in our nation's history to an end by issuing a formal apology on behalf of the United States Government.

The AIDS epidemic nationwide, the syphilis epidemic in the southern United States, and the lack of aggressive health care seeking behaviors among minority populations have all exposed the Tuskegee study as a historical marker for the legitimate discontent of Blacks with the public health system. According to Stephen B. Thomas, PhD and Sandra Crouse Quinn, MEd (*The Tuskegee Syphilis Study, 1932 to 1972: Implications for HIV Education and AIDS Risk Education Programs in the Black Community*, American Journal of Public Health, November 1991), "the belief that AIDS is a form of genocide is rooted in a social context in which many Americans, faced with persistent inequality, believe in conspiracy theories about Whites against Blacks. These theories range from the belief that the government promotes drug abuse in black communities to the belief that HIV is a manmade weapon of racial warfare. Almost 60 years after the study began, there remains a trail of distrust and suspicion that hampers HIV and STD prevention efforts in black communities."

At the time that this study became widely known to the public, the Public Health Service offered the survivors (and later their infected wives and children) penicillin and free medical treatment for life. Additionally, in 1974, a lawsuit filed on behalf of the victims was settled, awarding \$37,500 to each "living syphilitic" and \$15,00 to heirs of "deceased syphilitics." The nation's policies on research involving human subjects were also revised as a result of this study. Still there remains a great mistrust of our research and medical establishment that hinders the progress of our people. This mistrust is perpetuated because of the silence of our nation's leaders in directly speaking out on this issue.

The Institute of Medicine recently reported that with approximately 12 million new cases of STDs occurring annually (CDC, 1993), rates of curable STDs in the United States are the highest in the developed world (*The Hidden Epidemic: Confronting Sexually Transmitted Diseases*, Institute of Medicine, 1997). Moreover, while our

nation has made enormous progress in combating the AIDS epidemic, we continue to bear witness to the 40,000 new infections occurring yearly and the painful deaths of those Americans who will die of this disease. Sadly, the people least able to access the promising new treatments are poor, black men and women who already carry a historic alienation from our health care system.

As you begin your second term, committed to leading all of our people to the next century with a greater sense of freedom and justice, we hope that you will seize this historic moment to eradicate this vestige from our past.

Sincerely yours,

The National Association of People With AIDS (Washington, DC)
National Council of Negro Women (Washington, DC)
National Black Gay and Lesbian Leadership Forum (Washington, DC)
National Minority AIDS Council (Washington, DC)
AIDS Action Council (Washington, DC)
ACT UP/Atlanta (Atlanta, GA)
ACT UP/Cleveland (Cleveland, OH)
ACT UP/Golden Gate (San Francisco, CA)
ACT UP/Philadelphia (Philadelphia, PA)
African Services Committee, Inc. (New York, NY)
AIDS Medicine and Miracles (Boulder, CO)
AIDS Outreach Center of Ft. Worth (Fort Worth, TX)
AIDS Outreach Project (Everest, WA)
AIDS Task Force of Alabama (Birmingham, AL)
AIDS Housing of Washington (Seattle, WA)
AIDS Response Seacoast (Portsmouth, NH)
AIDS Project East Bay (Oakland, CA)
AIDS Foundation of San Diego (San Diego, CA)
AIDS Treatment Data Network (New York, NY)
AIDS Services of Dallas (Dallas, TX)
AIDS Ministry of Illinois (Joliet, IL)
AIDS Project Los Angeles (Los Angeles, CA)
AIDS-Manasota, Inc. (Sarasota, FL)
AIDS Law of Louisiana, Inc. (New Orleans, LA)
AIDS Foundation Houston, Inc (Houston, TX)
Arizona AIDS Foundation (Phoenix, AZ)
Asia Russell (Philadelphia, PA)
Asian and Pacific Islander Wellness Project (San Francisco, CA)
Bailey House (New York, NY)
Being Alive: The People with HIV/AIDS Action Coalition of L.A. (Los Angeles, CA)
Beth Israel Deaconess Medical Center (Boston, MA)
Beverly Forsyth (San Francisco, CA)
Black Educational AIDS Project, Inc.-Churches United Against AIDS (Balt., MD)

Blacks Assisting Blacks Against AIDS (St. Louis, MO)
Boulder County AIDS Project (Boulder, CO)
Brian Mills (Houston, TX)
Bruce Rashbaum, MD (Washington, DC)
C.A.R.E. Program (Long Beach, CA)
Cable Positive Ohio (Columbus, OH)
Cascade AIDS Project (Portland, OR)
Center for AIDS Prevention Studies, University of California (San Francisco, CA)
Central City AIDS Network, Inc. (Macon, GA)
Charles Hostetter, MD, MPH (San Francisco, CA)
Charles Wilson, D.P.M. (Silver Spring, MD)
Cheryl Nesbitt (Mitchellville, MD)
Children's Hospital (Oakland, CA)
City AIDS Actions (New York, NY)
Columbus Health Department (Columbus, OH)
Community AIDS Council of West Central Michigan (Grand Rapids, MI)
Concerned Citizens of Tillery (Tillery, NC)
Cure AIDS of Wilmington (Wilmington, NC)
Carolyn DeAngelis (Highland Park, NJ)
David Powell (Philadelphia, PA)
David Millstein (San Francisco, CA)
David Nimmons (New York, NY)
Department of Public Health, Maricopa County (Phoenix, AZ)
Diane Kholos Wysocki, Ph. D., University of Nebraska at Kearney (Kearney, NE)
Eastern Maine AIDS Network (Bangor, ME)
Ecumenical Information AIDS Resource Center (Philadelphia, PA)
Empowerment Program (Denver, CO)
Eric-Andrew Nadeau (Montreal, Can.)
Filipino Task Force on AIDS (San Francisco, CA)
Fort Worth Department of Public Health (Fort Worth, TX)
Franklin County/North Quabbin HIV/AIDS Consortium (Greenfield, MA)
Gail M. Millelsted, MPH, RN (San Antonio, TX)
Gary Costa (Los Angeles, CA)
Gay and Lesbian Community Center (Dallas, TX)
Gay and Lesbian Medical Association (San Francisco, CA)
Gay Men's Health Crisis, Inc. (New York, NY)
Genre Magazine (New York, NY)
Georgia AIDS Public Policy Network (Atlanta, GA)
Glenn Brown (Philadelphia, PA)
Gordon L. Snider, V. A. Medical Service (Boston, MA)
Gregory Relaford (New York, NY)
Harlem Congregation for Community Improvement, Inc. (Harlem, NY)
Harris County Health Department HIV Services (Houston, TX)
Haymarket House (Chicago, IL)
Health Crisis Network (Miami, FL)

HIV/AIDS Human Rights Project (New York, NY)
Housing Authority of the City of Hartford (Hartford, CT)
Individual Benefits, Inc. (Greensboro, NC)
International Association of Physicians in AIDS Care (Chicago, IL)
Jean Leach (Raleigh, NC)
Jeffrey Becker (Wilmington, NC)
Jennifer Winkler-University of Washington
Jeremy Landau, Member, President's Advisory Council on AIDS (Wash., DC)
Jerry Gates, Dir. Pacific AETC (Los Angeles, CA)
Judith Leibowitz (Silver Spring, MD)
Kathleen M. Quirk (San Francisco, CA)
Kevin P. Filocamo (San Francisco, CA)
Kevin Shipman, MHS, CAC (Laurel, MD)
Leo Rennie (New York, NY)
Linda Grinberg, Linda Grinberg Foundation (Los Angeles, CA)
Lori Delorenzo, MSN (Sterling, VA)
Marianne Scippa (Annapolis, MD)
Mark A. Colomb, Ph.D. (Mississippi Dept. Of Health-Jackson, MS)
Mary Lucey (Los Angeles, CA)
Mary Jane Rotheram, Ph. D. (Los Angeles, CA)
Memphis Planned Parenthood (Memphis, TN)
Mercy Hospital of Philadelphia (Philadelphia, PA)
Metro TeenAIDS (Washington, DC)
Michael Pizzi, OTR, CHES (Silver Spring, MD)
Mid Island AIDS Society (B.C., Canada)
Mississippi Department of Health (Jackson, MS)
Montefiore Hospital (Bronx, NY)
Montefiore Med Center (Bronx, NY)
Multicultural HIV/AIDS Alliance of Oregon (Portland, OR)
Nashville CARES (Nashville, TN)
National Black Lesbian and Gay Leadership Forum (Los Angeles, CA)
National Center for Lesbian Rights (San Francisco, CA)
National Council for International Health AIDS Program (Washington, DC)
National Native American AIDS Prevention Center (Oakland, CA)
New Jersey Buddies (Hackensack, NJ)
New York City Gay and Lesbian Anti-Violence Project (New York, NY)
Nightsweats and T-Cells, Co. (Kent, OH)
Northern New Mexico PLWA Coalition (Santa Fe, NM)
Northwest AIDS Foundation (Los Angeles, CA)
Outreach, Inc. (Delano, FL)
Pacific Treatment Alternatives (Everett, WA)
Paul Davis (Philadelphia, PA)
Philip Terry, Ph.D. (Laurel, MD)
Phill Wilson (Los Angeles, CA)
Postgraduate Center for Mental Health (New York, NY)

Project Inform (New York, NY)
Provincetown AIDS Support Group (Provincetown, MA)
Rosehedge (Seattle, WA)
San Francisco AIDS Foundation (San Francisco, CA)
Sherrie Smith, M.S.W. (Fairfax, VA)
Southwest Louisiana AIDS Council (Lake Charles, LA)
Substance Abuse Foundation (Long Beach, CA)
The Mujeres Project (Harlingen, TX)
The AIDS Project (Portland, ME)
The Gulf Coast Center HIV Division (Galveston, TX)
The Women's Center of Wake County (Raleigh, NC)
Training Resources Network (Silver Spring, MD)
Udo Schuklenk, Ph. D., University of Central Lancashire (Preston, UK)
University of Washington Center for AIDS & STD (Seattle, WA)
Walt Senterfitt (Los Angeles, CA)
Warren J. Blumenfeld-Journal of Gay, Lesbian and Bisexual Identity
We The People Living with AIDS/HIV of the Delaware Valley, Inc. (Phila., PA)
Western North Carolina AIDS Project (Asheville, NC)
Whitman Walker Clinic (Washington, DC)
Widney Brown (New York, NY)
William J. Woods, Ph. D. (San Francisco, CA)
World Institute on Disability (Oakland, CA)
Yale University (New Haven, CT)
YWCA of the USA (Washington, DC)



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Washington, DC
20005-3408
tel (202) 898-0414
fax (202) 898-0435
NAPWA FAX
(202) 789-2222
E-mail address:
napwa@thecure.org
Home page address:
<http://www.thecure.org>

NOTE FOR FEREDETTE WEST:

FROM: A. CORNELIUS BAKER *ACB*
SUBJECT: WHITE HOUSE CEREMONY
DATE: APRIL 9, 1997

Sorry, this took a little longer. Helene Gayle from CDC stopped by unexpectedly.

Here is a list of addresses for suggested invitees, including myself:

A. Cornelius Baker
Executive Director
NAPWA
1413 K Street, NW
Washington, DC 20005
202.898.0414

Paul Kawata
Executive Director
National Minority AIDS Council
1931 - 13th Street, NW
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